U.S. Department of Justice

United States Attorney
Western District of Virginia

STATEMENT OF UNITED STATES ATTORNEY JOHN BROWNLEE ON THE GUILTY PLEA OF THE PURDUE FREDERICK COMPANY AND ITS EXECUTIVES FOR ILLEGALLY MISBRANDING OXYCONTIN

May 10, 2007

One of the oldest and most challenging medical mysteries is the treatment of pain. For centuries, scientists and doctors have searched for a drug that would safely relieve patients of their chronic pain without inflicting the dangerous side effects that routinely come from the use of addictive narcotics. The discovery of this "wonder" drug would bring hope and relief to millions of suffering patients and wealth beyond one's imagination to its creators.

In 1996, Purdue and its top executives claimed that they had developed such a drug; a safe drug that would help those suffering in pain. The name of that drug was OxyContin. Backed by an aggressive marketing campaign, Purdue's OxyContin became the new pain medication of choice for many doctors and patients. Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.

But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew

its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures. OxyContin is nothing more than pure oxycodone – a habit forming narcotic derived from the opium poppy. Purdue's OxyContin never lived up to its hype and never offered a low risk way of reducing pain as promised. Simply put, the genesis of OxyContin was not the result of good science or laboratory experiment. OxyContin was the child of marketeers and bottom line financial decision making.

Accordingly, this morning, in a federal courtroom in Abingdon, Virginia, the Purdue Frederick Company, the manufacturer and distributor of OxyContin, pleaded guilty to a felony charge of illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers. Purdue has agreed to pay over $600 million in criminal and civil penalties, fines and forfeitures, subjected itself to independent monitoring and an extensive remedial action program, and acknowledged that it illegally marketed and promoted OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause withdrawal symptoms than other pain medications – all in an effort to maximize its profits. Also, Purdue's Chief Executive Officer Michael Friedman, General Counsel Howard Udell, and former Chief Medical Officer Paul Goldenheim pleaded guilty to a misdemeanor charge of misbranding OxyContin and collectively agreed to pay $34.5 million in penalties. With its OxyContin, Purdue unleashed a highly abusable, addictive, and potentially dangerous drug on an unsuspecting and unknowing public. For these misrepresentations and crimes, Purdue and its executives have been brought to justice.

We have released a Criminal Information, Plea Agreements, a Corporate Integrity Agreement, a Statement of Facts, and a Complaint for Forfeiture that have been filed in U.S. District Court in Abingdon. Purdue and its top three executives have pleaded guilty to illegally misbranding

OxyContin from 1996 thru 2001. The company has admitted that it misbranded OxyContin with the intent to defraud and mislead the public.

As part of this plea agreement, Purdue and its top three executives will pay $634.5 million in criminal and civil fines, penalties, and forfeitures, to be distributed as follows. First, Purdue will forfeit to the United States $276.1 million, a portion of which will be shared with the state and federal law enforcement agencies for their work during this investigation.

Second, Purdue will pay $130 million for compensation and settlement of private civil liabilities related to OxyContin. Any part of the $130 million that Purdue fails to distribute within two years will be immediately paid to the United States. Third, Purdue will pay $100.6 million to the United States as reimbursement for payments made by government agencies for the settlement of false claims related to the misbranding of OxyContin. Those federal agencies include the Department of Health and Human Services, the Department of Labor, the Department of Defense, the Office Personnel Management, and the Veterans Administration.

Fourth, Purdue will pay $59.3 million to the State Medicaid programs as reimbursement for payments made by Medicaid for the settlement of false claims related to the misbranding of OxyContin. This money is available to any state to settle claims related to Purdue's criminal conduct. Fifth, Purdue and its top three executives will pay $39.8 million to the Virginia Attorney General's Medicaid Fraud Control Unit Program Income fund. Virginia's MFCU is an important partner in our efforts to fight fraud against our medicaid programs. Sixth, Purdue will pay $20 million to the Virginia Department of Health Professionals' operation of the Virginia Prescription Monitoring Program. The prescription monitoring program was initiated in part because of the big spike in prescription drug abuse that accompanied the illegal marketing of OxyContin. Currently,

the program is largely funded by the Virginia taxpayers, and the $20 million payment by Purdue should endow the program for the foreseeable future. Seventh, Purdue will pay $4.6 million to cover the costs of the five year internal monitoring program that is a part of the company's Corporate Integrity Agreement with the Health and Human Services Office of the Inspector General. Eighth, Purdue will pay $3.4 million to the federal and state Medicaid programs for improperly calculated Medicaid rebates for years 1998 and 1999, and finally, Purdue and the three executives will pay $515,475 in criminal fines and special assessments to the court.

In addition to the guilty pleas and monetary penalties, the United States has directed Purdue, as part of the Corporate Integrity Agreement, to retain and pay for an Independent Monitor and staff to monitor Purdue's compliance with this agreement and federal law. The monitor and staff will be independent from Purdue's management and must file periodic reports with the government concerning Purdue's conduct and business practices. We believe this monitoring program, in conjunction with the Corporate Integrity Agreement, will ensure that in the future Purdue will market and promote its products in an honest and responsible manner. The public must be confident that we will keep close watch on how Purdue sells its most dangerous products.

I would now like to provide to you a brief summary of the investigation and some of our findings. The main violations of the law revealed by the government's criminal investigation are set forth in detail in the Statement of Facts released to you today.

The defendant The Purdue Frederick Company, a New York corporation headquartered in Connecticut, was created in 1892 and purchased by its current owners in 1952. Defendant Michael Friedman joined Purdue in 1985 and was appointed President and Chief Executive Officer in 2003. It is our understanding that Mr. Friedman has announced his intention to leave Purdue this year.

Defendant Howard Udell joined Purdue in 1977 and is presently Purdue's Executive Vice President and Chief Legal Officer. Defendant Dr. Paul Goldenheim joined Purdue in 1985 as its Medical Director. Dr. Goldenheim left Purdue in 2004.

This case began in early 1995, when Purdue used focus groups of primary care physicians and surgeons to determine whether physicians would be willing to prescribe OxyContin for patients with non-cancer pain. According to Purdue's research, many of these physicians had great reservations about prescribing OxyContin because of the drug's addictive potential and side effect profile, and its abuse potential. It was clear from these focus groups that physicians were concerned about the safety and risks of OxyContin.

Purdue also learned from these focus groups that physicians wanted a long lasting pain reliever that was less addictive and less subject to abuse and diversion. Purdue understood that the company that marketed and sold that drug would dominate the pain management market. And that is exactly what Purdue tried to do.

Despite knowing that OxyContin contained high concentrations of oxycodone HCL, had an abuse potential similar to that of morphine, and was at least as addictive as other pain medications on the market, Purdue, beginning in January 1996, with the intent to defraud and mislead, falsely marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. Purdue did so in the following ways:

First, Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse. Purdue ordered this training even though its own study showed that a drug abuser

could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

Second, Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction than immediate-release opioids.

Third, Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.

Fourth, Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug.

And fifth, Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

The results of Purdue's crimes were staggering. According to DEA, the number of oxycodone related deaths increased 400 percent between 1996 and 2001. During that same time period, the annual number of prescriptions for OxyContin increased from approximately 300,000 to nearly 6 million. Also, in February of 2002, the DEA released a report detailing the death rates caused by OxyContin abuse up to that time. According to the DEA, there were 146 deaths in which OxyContin was determined to be the direct "cause of" or "a contributing factor to." DEA identified an additional 318 deaths that were "most likely" caused by OxyContin. In Virginia, our medical examiner reported that 228 people died in western Virginia from overdoses of oxycodone from 1996

to 2005.

For some communities, the danger went beyond just addiction and death. Beginning in 2000, localities began to report dramatically higher crime rates – some up as much as 75% from the year before. This sharp increase in crime was directly attributable to the abuse of OxyContin. Tazewell County estimated that OxyContin was behind 80-95% of all crimes that were committed there. From 1998 to 2003, burglaries, robberies, and larcenies jumped 131% in Buchanan County and 102% in Russell County.

During the last 10 years, Virginia's law enforcement community has fought hard against the devastating effects OxyContin has had on our citizens and communities. During that time, we have convicted the OxyContin addicts who committed serious crimes to get money to buy more OxyContin, and we convicted street dealers who preyed upon the addicts' craving for this powerful narcotic. We also convicted pharmacists and physicians who illegally diverted OxyContin for personal gain and profit. With today's conviction of the maker of OxyContin, we have finally brought to justice the main component involved in this ring of abuse. The conviction of Purdue and its executives will end the misbranding and fraudulent marketing of OxyContin, deter other companies from committing like crimes, and provide desperately needed resources to fight addiction and abuse that threatens the health of millions of Virginians.

Thank you.

NEWS RELEASE

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THE PURDUE FREDERICK COMPANY, INC. AND TOP EXECUTIVES PLEAD GUILTY TO MISBRANDING OXYCONTIN, WILL PAY OVER $600 MILLION

John L. Brownlee, United States Attorney for the Western District of Virginia, and Virginia Attorney General Bob McDonnell announced today that The Purdue Frederick Company, Inc., along with its President, Chief Legal Officer, and former Chief Medical Officer have pleaded guilty to charges of misbranding Purdue's addictive and highly abusable drug OxyContin. Purdue and the three executives will pay a total of $634,515,475. OxyContin is a Schedule II prescription pain relief medication, classified as having the highest potential for abuse of legally available drugs. The Purdue Frederick Company, Inc., and the three executives have admitted that Purdue fraudulently marketed OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other pain medications when there was no medical research to support these claims and without Food and Drug Administration approval of these claims.

"Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted Oxycontin as less addictive, less subject to abuse, and less likely to cause withdrawal, " said United States Attorney John Brownlee. "In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less abusable, and less addictive than other pain medications on the market. Today's convictions are a testament to the outstanding work of the prosecutors and agents who spent years investigating this important case."

The Purdue Frederick Company, Inc. and Purdue Pharma, L.P. are part of a worldwide group of related and associated entities engaged in the pharmaceutical business. These entities manufacture, market, and distribute OxyContin, an extended-release form of oxycodone.

"Purdue put its desire to sell OxyContin above the interests of the public," said Assistant Attorney General Peter D. Keisler. "Purdue abused the drug approval process which relies on drug manufacturers to be forthright in reporting clinical data and, instead, misled physicians about the addiction and withdrawal issues involved with Oxycontin."

"The criminal behavior exhibited in this case damages the reputation of a critically important industry. Pharmaceutical companies have an obligation to patients, physicians, and those in the industry they serve to market prescription drugs in accordance with the law and FDA regulations." said Virginia Attorney General Bob McDonnell, " I applaud John Brownlee and his team for their leadership, as well as the Virginia Medicaid Fraud Control Unit, FDA and all of the other state and federal law enforcement agencies that worked so hard over the past four years to investigate this complex criminal scheme and bring the wrongdoers to justice."

"FDA will not tolerate practices that falsely promote drug products and place consumers at health risk," said Margaret O.K. Glavin, Associate Commissioner for Regulatory Affairs, FDA. "We will continue to do all we can to protect the public against drug companies and their representatives who are not truthful and bilk consumers of precious health care dollars."

The Purdue Frederick Company, Inc., pleaded guilty to felony misbranding OxyContin with the intent to defraud and mislead. President and Chief Operating Officer Michael Friedman, Executive Vice President and Chief Legal Officer Howard Udell, and former Executive Vice President of Worldwide Medical Affairs Paul D. Goldenheim, pleaded guilty to a misdemeanor charge of misbranding OxyContin. All the pleas were entered in United States District Court in Abingdon this morning.

"Purdue's illegal sales and marketing practices concealed information from patients and many health care providers regarding the potency and abuse potential of OxyContin for corporate profit," said Daniel R. Levinson, Inspector General for the U.S. Department of Health and Human Services. "We commend the highly qualified team of prosecutors and investigators from a variety of Federal and State agencies for developing a global resolution that addresses the criminal violations of the past, ensures strict compliance in the future, and serves as a strong warning to others who may consider illegally marketing pharmaceuticals."

"The falsification of drug product information is a very serious breach of the public's trust. IRS Criminal Investigation will continue to concentrate its resources on the tax and money laundering aspects of these types of investigations in cooperation with the United States Attorney's Office and other federal, state, and local authorities," said Charles R. Pine, Special Agent in Charge.

"Today's guilty pleas mark a significant milestone in the fight against corruption by company officials who seek to illegally enrich corporate profits at taxpayers' expense," stated Gordon S. Heddell, Inspector General, U.S. Department of Labor. "These convictions demonstrate our steadfast resolve to investigate any individuals who would defraud Labor programs, such as the Office of Workers' Compensation Programs, by overcharging them. My office remains committed to working with other law enforcement agencies and the U.S. Attorney to fight this type of corruption."

Pursuant to written plea agreements, Purdue and the executives will pay a total of $634,515,475.00. Purdue's payments will include:

$276.1 million forfeited to the United States

$160 million paid to federal and state government agencies to resolve liability for false claims made to Medicaid and other government healthcare programs

$130 million set aside to resolve private civil claims (monies remaining after 36 months will be paid to the United States)

$5.3 million paid to the Virginia Attorney General's Medicaid Fraud Control Unit to fund future health care fraud investigations

$20 million paid to fund the Virginia Prescription Monitoring Program for the foreseeable future

In addition, Purdue will pay the maximum statutory criminal fine of $500,000.

Purdue's top executives will pay the following amounts to the Virginia Attorney General's Medicaid Fraud Control Unit:

$19 million paid by Michael Friedman

$8 million paid by Howard R. Udell

$7.5 million paid by Dr. Paul D. Goldenheim

Each executive will also pay a $5,000 criminal fine.

The Director of the Defense Criminal Investigative Service, Mr. Chuck Beardall, stated, "It is unthinkable that purely for greed, addictive drugs were fraudulently marketed to the public, and in so doing threatened the health and safety of our citizens. Among those endangered were soldiers, sailors, airmen, marines, and their families, all of whom avail themselves of the military health system. At a time when our military personnel and their loved ones are sacrificing so much, something like this is incomprehensible and grossly reprehensible."

According to the Statement of Facts filed with the Court, beginning in January 1996 and continuing through June 30, 2001, Purdue's market research found that "[t]he biggest negative of [OxyContin] was the abuse potential." Despite this finding, Purdue's supervisors and employees falsely and misleadingly marketed OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal than other pain medications. Purdue misbranded OxyContin in three specific ways:

1. Purdue sales representatives falsely told some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids. This message was

presented to some health care providers through the use of graphs that exaggerated the differences between blood plasma levels achieved by OxyContin compared to the levels of other pain relief medications. Purdue supervisors and employees participated in the misbranding in the following ways:

A. Purdue supervisors and employees sponsored training that used graphs that exaggerated the differences between the blood plasma levels of OxyContin as compared to immediate-release opioids. These graphs were used to falsely teach Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids and that would result in less euphoria and less potential for abuse than short-acting opioids.

B. Purdue supervisors and employees permitted new Purdue sales representatives to use similar exaggerated graphical depictions during role-play training at Purdue's headquarters in Stamford, Connecticut.

2. Purdue supervisors and employees drafted an article about a study of the use of OxyContin in osteoarthritis patients that was published in a medical journal on March 27, 2000. On June 26, 2000, each sales representative was provided a copy of the article together with a "marketing tip" that stated that the article was available for use in achieving sales success. Sales representatives distributed copies of the article to health care providers to falsely or misleadingly represent that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms. The article also indicated that patients on such doses would not develop tolerance. The marketing tip that accompanied the article stated that one of the twelve key points was, "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR [controlled release] oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d [milligrams per day] can be discontinued without tapering the dose if the patient condition so warrants." These marketing claims were made even though Purdue representatives were well aware of the following information:

A. The year before the article was published and distributed to sales representatives, Purdue received an analysis of the osteoarthritis study and a second study from a United Kingdom company affiliated with Purdue that listed eight patients in the osteoarthritis study "who had symptoms recorded that may possibly have been related to opioid withdrawal," and stated that "[a]s expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

B. In May of 2000, Purdue received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms. Executives also learned that "this type of question,

patients not being able to stop OxyContin without withdrawal symptoms ha[d] come up quite a bit . . . in Medical Services lately (at least 3 calls in the last 2 days)."

C. In February 2001, Purdue received a review of the accuracy of the withdrawal data in the osteoarthritis study that listed eleven study patients who reported adverse experience due to possible withdrawal symptoms during the study's respite periods and stated "[u]pon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms;" Even after receiving this information, on March 28, 2001, supervisors and employees decided not to write up the findings because of a concern that it might "add to the current negative press."

D. Supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger to or equal to morphine" or to "take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians['] mind[s]."

3. Purdue sales representatives, while promoting and marketing OxyContin, falsely told health care providers that the statement in the OxyContin package insert that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug," meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

The statement was later amended to read, "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug." Nevertheless, Purdue continued to market OxyContin in the same manner as described above.

Purdue supervisors and employees took part in the misbranding in the following ways:

A. Supervisors instructed Purdue sales representatives to use the reduced abuse liability statement and the amended statement to market and promote OxyContin.

B. Supervisors told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chances for addiction than immediate-release opioids.

C. Supervisors trained Purdue sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although Purdue's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet merely by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

D. By March 2000, Purdue had received reports of OxyContin abuse and diversion occurring in different communities but allowed sales staff to continue promoting and marketing OxyContin in this manner.

The case was investigated by the Virginia Attorney General's Medicaid Fraud Control Unit; Food and Drug Administration, Office of Criminal Investigations; Internal Revenue Service Criminal Investigation; the Department of Health and Human Services Office of Inspector General; Department of Labor, Office of Inspector General; Defense Criminal Investigative Service; Virginia State Police; and West Virginia State Police. The case was prosecuted by Assistant United States Attorneys Rick Mountcastle, Randy Ramseyer and Sharon Burnham and U.S. Department of Justice, Office of Consumer Litigation, Trial Attorneys Barbara Wells and Elizabeth Stein.

END

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Dkt. No. _____**
	)	
THE PURDUE FREDERICK COMPANY, INC.	)	**21 U.S.C. §§ 331(a), 352(a), 333(a)(2)**
D/B/A The Purdue Frederick Company	)	
MICHAEL FRIEDMAN	)	**21 U.S.C. §§ 331(a), 352(a), 333(a)(1)**
HOWARD R. UDELL	)	**21 U.S.C. §§ 331(a), 352(a), 333(a)(1)**
PAUL D. GOLDENHEIM	)	**21 U.S.C. §§ 331(a), 352(a), 333(a)(1)**

INFORMATION

INTRODUCTION

The United States Attorney charges that at all times relevant to this Information:

Description of Defendants

1. Defendant The PURDUE FREDERICK COMPANY, INC. (referred to in this Information as "PURDUE"), doing business as The Purdue Frederick Company, was a New York corporation, headquartered in Connecticut. It was created in 1892 and was purchased by its current owners in 1952. At all times relevant to this Information, PURDUE and other related and associated entities were engaged in the pharmaceutical business throughout the United States.

2. PURDUE developed and originally marketed OxyContin Tablets ("OxyContin"), an opioid analgesic approved to be taken every twelve hours. OxyContin is a controlled-release form of oxycodone and is a Schedule II controlled substance with an abuse liability similar to morphine.

3. Defendant MICHAEL FRIEDMAN joined PURDUE in 1985 as Vice President and Assistant to the President and Chairman. He was appointed Group Vice President in 1988, Executive Vice President and Chief Operating Officer in 1999, and President and Chief Executive

Officer in 2003.

4. Defendant HOWARD R. UDELL joined PURDUE in 1977 as General Counsel. He was appointed Group Vice President and General Counsel in 1989, Executive Vice President and General Counsel in 1999, and Executive Vice President and Chief Legal Officer in 2003.

5. Defendant PAUL D. GOLDENHEIM joined PURDUE in 1985 as Medical Director. He was appointed Vice President and Medical Director in 1986, Vice President of Scientific and Medical Affairs and Executive Director of Purdue Frederick Research Center in 1988, Group Vice President of Scientific and Medical Affairs in 1989, Executive Vice President of Medical and Scientific Affairs in 1999, Executive Vice President of Worldwide Research & Development in 2000, and Executive Vice President of Worldwide Research & Development and Chief Scientific Officer in 2003. He left PURDUE in 2004.

6. From January 1996 through June 30, 2001, PURDUE received approximately $2.8 billion in revenue from the sale of OxyContin.

Statutory Framework

7. The United States Food and Drug Administration ("FDA") is the agency of the United States responsible for protecting the public health by ensuring the safety, efficacy, and security of human drugs and for enforcing the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*

8. The FDCA, 21 U.S.C. § 355, required a sponsor of a new drug to receive FDA approval of a New Drug Application ("NDA"), before the sponsor could distribute the drug in interstate commerce.

9. The FDCA, 21 U.S.C. § 321(m), defined labeling to include "all labels and other

written, printed, or graphic matter . . . accompanying [a drug]." Title 21, Code of Federal Regulations, Section 202.1(*l*)(2) provided that labeling included brochures, booklets, mailing pieces, detailing pieces, bulletins, letters, motion picture films, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug which were disseminated by or on behalf of a drug's manufacturer, packer, or distributor. Such items "accompanied" a drug if they were designed for use and used in the distribution and sale of the drug.

10. The FDCA, 21 U.S.C. § 352(a), provided that a drug was misbranded "[i]f its labeling [was] false or misleading in any particular." The FDCA, 21 U.S.C. § 321(n), provided that "[i]n determining whether the labeling . . . [was] misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use . . . to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual."

11. The FDCA, 21 U.S.C. § 331(a), prohibited the introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 333(a)(2) provided that such a violation committed with the intent to defraud or mislead was punishable as a felony. Under 21 U.S.C. § 333(a)(1) and the applicable case law, an individual could be held criminally liable for a misdemeanor violation of § 331(a) without having knowledge of, or intent to cause, the misbranding if that individual was a responsible corporate officer at the time of the misbranding. A responsible corporate officer for these purposes was one who had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the

misbranding of a drug introduced or delivered for introduction into interstate commerce.

12. OxyContin was a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and a new drug within the meaning of 21 U.S.C. § 321(p).

OxyContin Approval and Package Insert

13. On approximately December 28, 1994, PURDUE submitted the OxyContin NDA to the FDA. The NDA included clinical studies showing that OxyContin, when dosed every twelve hours, was as safe and as effective as immediate-release oxycodone dosed every six hours.

14. The NDA did not claim that OxyContin was safer or more effective than immediate-release oxycodone or other pain medications and PURDUE did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications.

15. On or about October 24, 1995, the FDA completed, with PURDUE's assistance, an internal Medical Officer Review ("MOR") of the Integrated Summary of Safety ("ISS") and a MOR of the Integrated Summary of Efficacy ("ISE"). While not binding on the company, the MORs were disclosed to certain PURDUE supervisors and employees. These MORs did not state that OxyContin was more effective than or superior to, safer, had less opioid effects, or caused fewer adverse events than any other marketed product.

16. The MOR of the ISS included these statements:

a. "The blood level data in clinical use suggests the opioid effects [of OxyContin and immediate-release oxycodone] would be similar;"

b. "The best conclusion is that the efficacy of [OxyContin] is equivalent to the [immediate-release oxycodone], with an adverse event profile that is as good as the [immediate-release oxycodone]. I would not allow a 'better' claim." (emphasis in original);

c. "The adverse experience profile of [OxyContin] is qualitatively similar to that of the parent drug, oxycodone;" and

d. "Withdrawal is possible in patients who have their dosage abruptly reduced or discontinued."

17. The MOR of the ISE included these statements:

a. "There is some evidence, both pharmacokinetic and clinical, that reduced acute opioid adverse effects may be expected in some patients, but there is not enough evidence to support an [adverse event] superiority claim [for OxyContin] against other marketed products." (emphasis in original); and

b. "Care should be taken to limit competitive promotion. [OxyContin] has been shown to be as good as current therapy, but has not been shown to have a significant advantage beyond reduction in frequency of dosing."

18. The FDA approved the OxyContin NDA on December 12, 1995, and from 1996 through June 30, 2001, the FDA-approved package insert for OxyContin stated that it was intended for "the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." The package insert also included the statement: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."

Misbranding of OxyContin

19. During the period February through March 1995, PURDUE supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain. According to this market research, some of these physicians had concerns, similar to their concerns about combination opioids, regarding OxyContin's addictive potential and side effect profile, including that "[t]he biggest negative of [OxyContin] was the abuse potential."

20. Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed

and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:

a. Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;

b. Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;

c. Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

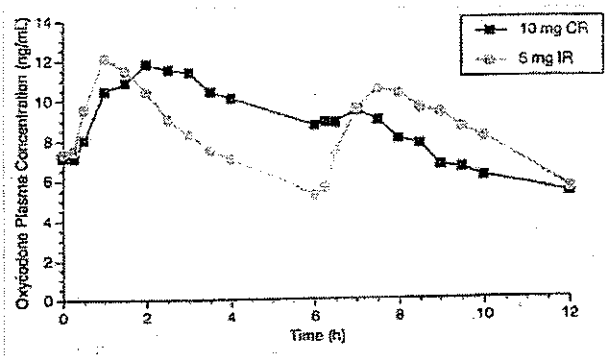
d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

e. Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

Misbranding of OxyContin: Use of Graphical Depictions by Sales Representatives

21. Data from one of PURDUE's clinical studies was used to create the following graphical demonstration of the difference in the plasma levels at steady state between patients who

took OxyContin every twelve hours (the "10 mg CR" line) and patients who took immediate-release oxycodone every six hours (the "5 mg IR" line):



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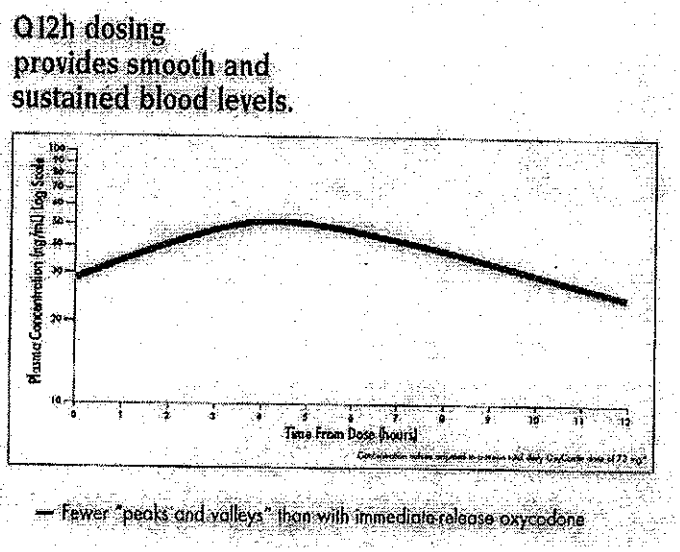

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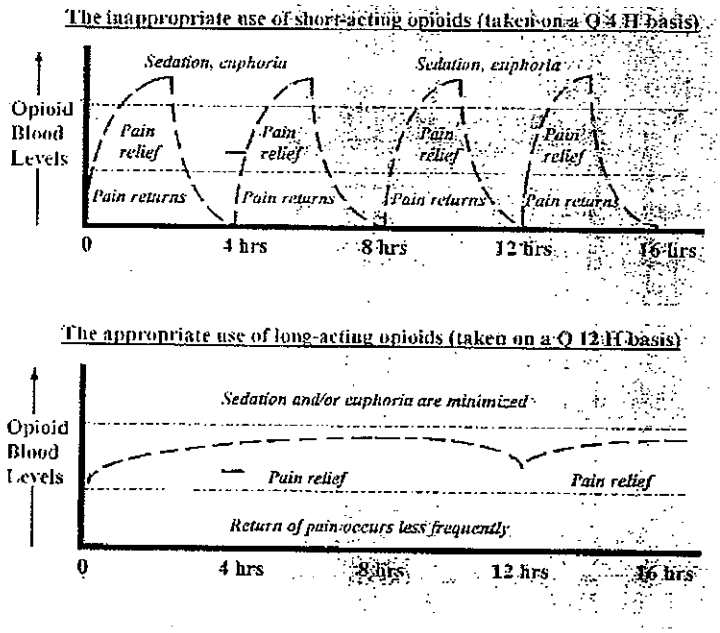

26. Beginning in or around 1999, some of PURDUE's new sales representatives were permitted, during training at PURDUE's headquarters, to draw their own blood level graphs to falsely represent that OxyContin, unlike immediate-release or short-acting opioids, did not swing up and down between euphoria and pain and resulted in less abuse potential.

27. During the period 1999 through June 30, 2001, certain PURDUE sales representatives used graphical depictions similar to the one described in paragraph 25 of the Introduction of this Information and falsely stated to some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids.

Misbranding of OxyContin: Misleading Use of Article to Claim No Withdrawal or Tolerance

28. On or about January 16, 1997, certain PURDUE supervisors and employees sent to the FDA the results of a clinical study pertaining to the use of low doses of OxyContin by

osteoarthritis patients ("osteoarthritis study") and a final study report that included, in a section pertaining to respite periods, the statement "[n]o investigator reported 'withdrawal syndrome' as an adverse experience during the respite periods." In a section entitled "Adverse Experiences by Body System During Respite Periods," the report's summary of the major results listed the most frequently reported adverse experiences in respite periods to be nervousness, insomnia, nausea, pain, anxiety, depression, and diarrhea, followed by the statement: "Twenty-eight patients (26%) had symptoms recorded during 1 or more respite periods."

29. In or about May 1997, certain PURDUE supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger or equal to morphine" or to "take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians mind (*sic*)."

30. On or about February 12, 1999, certain supervisors and employees of a United Kingdom company affiliated with PURDUE provided certain PURDUE supervisors and employees with an analysis of the osteoarthritis study together with another clinical study. This analysis included a list of eight patients in the osteoarthritis study and eleven patients in the other study "who had symptoms recorded that may possibly have been related to opioid withdrawal," including one patient in the other study who required treatment for withdrawal syndrome. The "Discussion" section of this analysis included the following: "It is not surprising that some patients in the clinical trials developed some degree of physical dependence and consequently experienced withdrawal symptoms as a result of abrupt discontinuation of OxyContin tablets. All patients who were

suspected to have withdrawal symptoms have been reported but this may have resulted in a falsely high incidence. Of the patients who participated in [the osteoarthritis study] (in which patients entered respite periods without OxyContin tablets) many symptoms suspected to be due to opioid withdrawal may simply have resulted from the return of pain. After withdrawal of OxyContin tablets, patient 6007 complained of nervousness, patient 2004 complained of insomnia and felt restless and patients 2020 and 2028 were restless and anxious. Since these are symptoms which often accompany the return of significant pain, it may be wrong to label these as withdrawal symptoms. Nonetheless, the incidence of withdrawal syndromes in patients treated with OxyContin tablets is a concern and it is safer to over report, than under report this potential problem." The analysis' conclusions included the statement: "As expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

31. Certain PURDUE supervisors and employees participated in the drafting of an article regarding the osteoarthritis study that was published in a medical journal on or about March 27, 2000 ("osteoarthritis study article"). The "Results" section of the article included the following three statements pertaining to the incidence of withdrawal syndrome and withdrawal symptoms experienced by study patients: (1) One patient was hospitalized "for withdrawal symptoms . . . . The patient who was hospitalized with withdrawal symptoms had completed the study on the previous day and had been receiving CR oxycodone, 70 mg/d; symptoms resolved after 3 days." (2) "A second patient, who was receiving 60 mg/d CR oxycodone, experienced withdrawal symptoms after running out of study medication. The patient had not reported withdrawal symptoms during scheduled respites from doses of 30 or 40 mg/d." (3) "Withdrawal syndrome was not reported as

an adverse event for any patient during scheduled respites. Adverse experiences reported by more than 10% of patients during scheduled respites were nervousness (9 patients) and insomnia (8 patients)."

32. The osteoarthritis study article also included a "Comment" section. The statement regarding withdrawal in this section largely summarized the information in the three statements in the "Results" section and further suggested that patients taking low doses could have their OxyContin treatment abruptly discontinued without experiencing withdrawal if their condition so warranted: "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites, indicating that [OxyContin] at doses below 60 mg [per day] can be discontinued without tapering the dose if the patient's condition so warrants."

33. On or about May 18, 2000, after millions of OxyContin tablets had been sold and used by patients, PURDUE's Medical Services Department reported to certain PURDUE supervisors and employees that it had recently received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms and the report indicated that "this type of question, patients not being able to stop OxyContin without withdrawal symptoms has come up quite a bit here in Medical Services lately (at least 3 calls in the last 2 days)."

34. On or about June 26, 2000, certain PURDUE supervisors and employees sent the full text of the osteoarthritis study article together with a "marketing tip" to PURDUE's entire sales force. The marketing tip stated that a reprint of the osteoarthritis study article was available for use in achieving sales success. The marketing tip also included as one of the article's twelve key points:

"There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d can be discontinued without tapering the dose if the patient condition so warrants."

35. On or about February 13, 2001, certain PURDUE supervisors and employees received a review of the accuracy of the withdrawal data in the osteoarthritis study that stated: "Upon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms." This was followed by a list of eleven study patients who reported adverse experience due to possible withdrawal symptoms during these periods. 106 patients initially participated in the osteoarthritis study, 32 of them withdrew because of adverse events (not necessarily related to withdrawal), and 38 patients remained in the study at 12 months.

36. On or about March 28, 2001, a PURDUE employee emailed a PURDUE supervisor regarding the review of withdrawal data described in paragraph 35 of the Introduction of this Information, asking: "Do you think the withdrawal data from the [osteoarthritis] study . . . is worth writing up (an abstract)? Or would this add to the current negative press and should be deferred?" The supervisor responded: "I would not write it up at this point." No abstract was prepared.

37. Between approximately June 26, 2000, and June 30, 2001, certain PURDUE supervisors and employees distributed copies of the reprint of the osteoarthritis study article to all of PURDUE's sales representatives for use in the promotion and marketing of OxyContin to health care providers, including the distribution of 10,615 copies to certain PURDUE sales representatives between February 13, 2001, and June 30, 2001.

38. During the period June 26, 2000, through June 30, 2001, certain PURDUE sales representatives distributed the reprint of the osteoarthritis study article to some health care providers and falsely or misleadingly stated that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms and that patients on such doses would not develop tolerance.

Misbranding of OxyContin: Use of Reduced Abuse Liability Claim in Marketing

39. The original OxyContin package insert approved by the FDA stated: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug" (the *Reduced Abuse Liability Statement*). Certain PURDUE supervisors and employees instructed PURDUE sales representatives to use this statement to market and promote OxyContin.

40. Certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

41. By March 2000, various PURDUE supervisors and employees in different parts of the company had received reports of OxyContin abuse and diversion occurring in different communities.

42. On or about November 27, 2000, certain PURDUE supervisors and employees amended the *Reduced Abuse Liability Statement* to state that "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug," and instructed PURDUE sales representatives to use the amended statement to

promote and market OxyContin.

43. From March 2000 through June 30, 2001, certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* and the amended statement meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

COUNT ONE
Introduction of Misbranded Drug into Interstate Commerce
21 U.S.C. §§ 331(a), 352(a), 333(a)(2)

1. The Introduction of this Information is realleged and made a part of this Count.

2. In or about and between January 1996 and June 30, 2001, in the Western District of Virginia and elsewhere, defendant The PURDUE FREDERICK COMPANY, INC. doing business as The Purdue Frederick Company, with the intent to defraud or mislead, introduced and caused the introduction into interstate commerce of quantities of OxyContin from various locations outside the state of Virginia to various locations in the Western District of Virginia and elsewhere, which were misbranded within the meaning of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(a), in that the matters described in paragraphs 19 through 43 of the Introduction of this Information constituted labeling within the meaning of 21 U.S.C. § 321(m) and were false and/or misleading.

All in violation of 21 U.S.C. §§ 331(a), 352(a), and 333(a)(2).

COUNT TWO
Introduction of Misbranded Drug in Interstate Commerce
21 U.S.C. §§ 331(a), 352(a), and 333(a)(1)

The United States Attorney charges that:

1. The Introduction of this Information is realleged and made a part of this Count.

2. Between in or about January 1996 and on or about June 30, 2001, defendants MICHAEL FRIEDMAN, HOWARD R. UDELL, and PAUL D. GOLDENHEIM, were senior executives of The PURDUE FREDERICK COMPANY, INC., doing business as The Purdue Frederick Company, and were responsible corporate officers under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a) during the time that THE PURDUE FREDERICK COMPANY, INC., introduced and caused the introduction into interstate commerce of quantities of OxyContin from various locations outside the state of Virginia to various locations in the Western District of Virginia and elsewhere, which were misbranded as described in paragraphs 19 through 43 of the Introduction and Count One of this Information.

All in violation of Title 21, United States Code, Sections 331(a), 352(a), and 333(a)(1).

Date: May 9, 2007

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Dkt. No. _____**
	)	
THE PURDUE FREDERICK COMPANY, INC.	)	
D/B/A The Purdue Frederick Company	)	
MICHAEL FRIEDMAN	)	
HOWARD R. UDELL	)	
PAUL D. GOLDENHEIM	)	

AGREED STATEMENT OF FACTS

Introduction

1. Defendant The PURDUE FREDERICK COMPANY, INC. (referred to in this Agreed Statement of Facts as "PURDUE"), doing business as The Purdue Frederick Company, was a New York corporation, headquartered in Connecticut. It was created in 1892 and was purchased by its current owners in 1952. At all times relevant to this Agreed Statement of Facts, PURDUE and other related and associated entities were engaged in the pharmaceutical business throughout the United States.

2. PURDUE developed and originally marketed OxyContin Tablets ("OxyContin"), an opioid analgesic approved to be taken every twelve hours. OxyContin is a controlled-release form of oxycodone and is a Schedule II controlled substance with an abuse liability similar to morphine.

3. Defendant MICHAEL FRIEDMAN joined PURDUE in 1985 as Vice President and Assistant to the President and Chairman. He was appointed Group Vice President in 1988, Executive Vice President and Chief Operating Officer in 1999, and President and Chief Executive Officer in 2003.

4. Defendant HOWARD R. UDELL joined PURDUE in 1977 as General Counsel. He was appointed Group Vice President and General Counsel in 1989, Executive Vice President and General Counsel in 1999, and Executive Vice President and Chief Legal Officer in 2003.

5. Defendant PAUL D. GOLDENHEIM joined PURDUE in 1985 as Medical Director. He was appointed Vice President and Medical Director in 1986, Vice President of Scientific and Medical Affairs and Executive Director of Purdue Frederick Research Center in 1988, Group Vice President of Scientific and Medical Affairs in 1989, Executive Vice President of Medical and Scientific Affairs in 1999, Executive Vice President of Worldwide Research & Development in 2000, and Executive Vice President of Worldwide Research & Development and Chief Scientific Officer in 2003. He left PURDUE in 2004.

6. From January 1996 through June 30, 2001, PURDUE received approximately $2.8 billion in revenue from the sale of OxyContin.

Statutory Framework

7. The United States Food and Drug Administration ("FDA") is the agency of the United States responsible for protecting the public health by ensuring the safety, efficacy, and security of human drugs and for enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*

8. The FDCA, 21 U.S.C. § 355, required a sponsor of a new drug to receive FDA approval of a New Drug Application ("NDA"), before the sponsor could distribute the drug in interstate commerce.

9. The FDCA, 21 U.S.C. § 321(m), defined labeling to include "all labels and other written, printed, or graphic matter . . . accompanying [a drug]." Title 21, Code of Federal

Regulations, Section 202.1(*l*)(2) provided that labeling included brochures, booklets, mailing pieces, detailing pieces, bulletins, letters, motion picture films, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug which were disseminated by or on behalf of a drug's manufacturer, packer, or distributor. Such items "accompanied" a drug if they were designed for use and used in the distribution and sale of the drug.

10. The FDCA, 21 U.S.C. § 352(a), provided that a drug was misbranded "[i]f its labeling [was] false or misleading in any particular." The FDCA, 21 U.S.C. § 321(n), provided that "[i]n determining whether the labeling . . . [was] misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use . . . to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual."

11. The FDCA, 21 U.S.C. § 331(a), prohibited the introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 333(a)(2) provided that such a violation committed with the intent to defraud or mislead was punishable as a felony. Under 21 U.S.C. § 333(a)(1) and the applicable case law, an individual could be held criminally liable for a misdemeanor violation of § 331(a) without having knowledge of, or intent to cause, the misbranding if that individual was a responsible corporate officer at the time of the misbranding. A responsible corporate officer for these purposes was one who had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce.

12. OxyContin was a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and a new drug within the meaning of 21 U.S.C. § 321(p).

OxyContin Approval and Package Insert

13. On approximately December 28, 1994, PURDUE submitted the OxyContin NDA to the FDA. The NDA included clinical studies showing that OxyContin, when dosed every twelve hours, was as safe and as effective as immediate-release oxycodone dosed every six hours.

14. The NDA did not claim that OxyContin was safer or more effective than immediate-release oxycodone or other pain medications and PURDUE did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications.

15. On or about October 24, 1995, the FDA completed, with PURDUE's assistance, an internal Medical Officer Review ("MOR") of the Integrated Summary of Safety ("ISS") and a MOR of the Integrated Summary of Efficacy ("ISE"). While not binding on the company, the MORs were disclosed to certain PURDUE supervisors and employees. These MORs did not state that OxyContin was more effective than or superior to, safer, had less opioid effects, or caused fewer adverse events than any other marketed product.

16. The MOR of the ISS included these statements:

a. "The blood level data in clinical use suggests the opioid effects [of OxyContin and immediate-release oxycodone] would be similar;"

b. "The best conclusion is that the efficacy of [OxyContin] is equivalent to the [immediate-release oxycodone], with an adverse event profile that is as good as the [immediate-release oxycodone]. I would not allow a 'better' claim." (emphasis in original);

c. "The adverse experience profile of [OxyContin] is qualitatively similar to that of the parent drug, oxycodone;" and

d. "Withdrawal is possible in patients who have their dosage abruptly reduced or discontinued."

17. The MOR of the ISE included these statements:

a. "There is some evidence, both pharmacokinetic and clinical, that reduced acute opioid adverse effects may be expected in some patients, but there is not enough evidence to support an [adverse event] superiority claim [for OxyContin] against other marketed products." (emphasis in original); and

b. "Care should be taken to limit competitive promotion. [OxyContin] has been shown to be as good as current therapy, but has not been shown to have a significant advantage beyond reduction in frequency of dosing."

18. The FDA approved the OxyContin NDA on December 12, 1995, and from 1996 through June 30, 2001, the FDA-approved package insert for OxyContin stated that it was intended for "the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." The package insert also included the statement: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."

Misbranding of OxyContin

19. During the period February through March 1995, PURDUE supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain. According to this market research, some of these physicians had concerns, similar to their concerns about combination opioids, regarding OxyContin's addictive potential and side effect profile, including that "[t]he biggest negative of [OxyContin] was the abuse potential."

20. Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to

cause tolerance and withdrawal than other pain medications, as follows:

a. Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;

b. Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;

c. Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

e. Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

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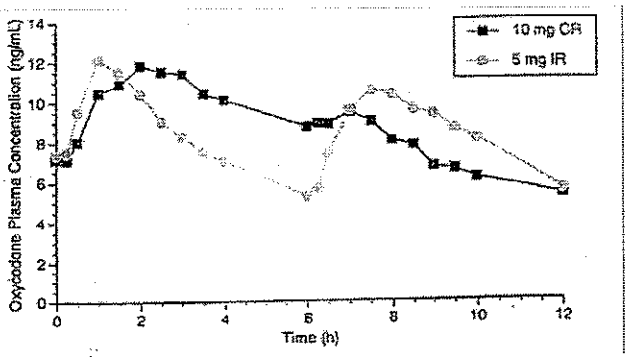

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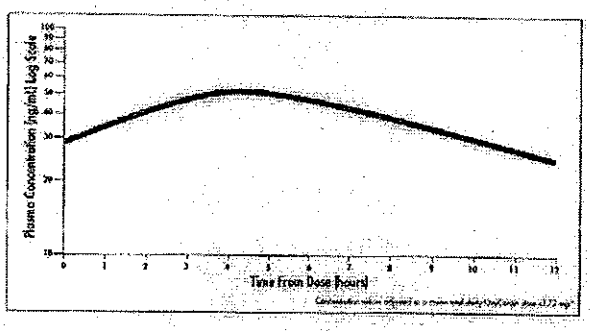
Q12h dosing provides smooth and sustained blood levels.



— Fewer "peaks and valleys" than with immediate-release oxycodone

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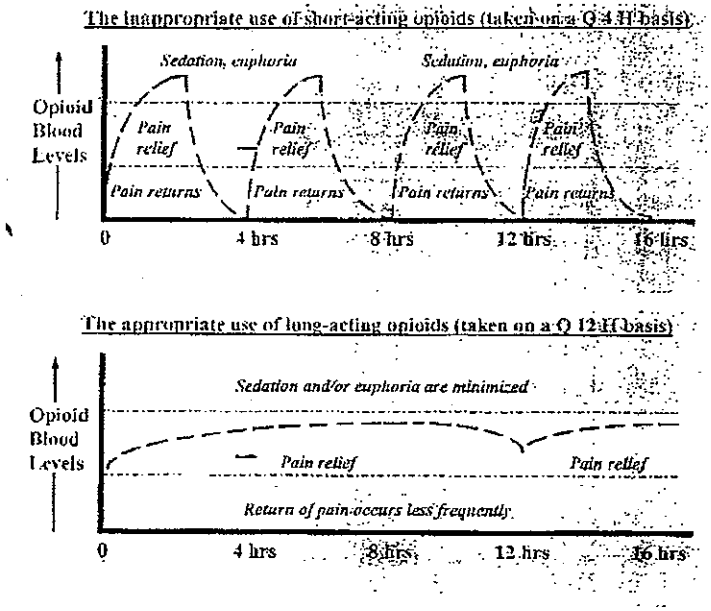

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27. During the period 1999 through June 30, 2001, certain PURDUE sales representatives used graphical depictions similar to the one described in paragraph 25 of this Agreed Statement of Facts and falsely stated to some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids.

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29. In or about May 1997, certain PURDUE supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger or equal to morphine" or to "take any steps in the form of promotional materials, symposia, clinicals,

publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians mind (*sic*)."

30. On or about February 12, 1999, certain supervisors and employees of a United Kingdom company affiliated with PURDUE provided certain PURDUE supervisors and employees with an analysis of the osteoarthritis study together with another clinical study. This analysis included a list of eight patients in the osteoarthritis study and eleven patients in the other study "who had symptoms recorded that may possibly have been related to opioid withdrawal," including one patient in the other study who required treatment for withdrawal syndrome. The "Discussion" section of this analysis included the following: "It is not surprising that some patients in the clinical trials developed some degree of physical dependence and consequently experienced withdrawal symptoms as a result of abrupt discontinuation of OxyContin tablets. All patients who were suspected to have withdrawal symptoms have been reported but this may have resulted in a falsely high incidence. Of the patients who participated in [the osteoarthritis study] (in which patients entered respite periods without OxyContin tablets) many symptoms suspected to be due to opioid withdrawal may simply have resulted from the return of pain. After withdrawal of OxyContin tablets, patient 6007 complained of nervousness, patient 2004 complained of insomnia and felt restless and patients 2020 and 2028 were restless and anxious. Since these are symptoms which often accompany the return of significant pain, it may be wrong to label these as withdrawal symptoms. Nonetheless, the incidence of withdrawal syndromes in patients treated with OxyContin tablets is a concern and it is safer to over report, than under report this potential problem." The analysis' conclusions included the statement: "As expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

31. Certain PURDUE supervisors and employees participated in the drafting of an article regarding the osteoarthritis study that was published in a medical journal on or about March 27, 2000 ("osteoarthritis study article"). The "Results" section of the article included the following three statements pertaining to the incidence of withdrawal syndrome and withdrawal symptoms experienced by study patients: (1) One patient was hospitalized "for withdrawal symptoms .... The patient who was hospitalized with withdrawal symptoms had completed the study on the previous day and had been receiving CR oxycodone, 70 mg/d; symptoms resolved after 3 days." (2) "A second patient, who was receiving 60 mg/d CR oxycodone, experienced withdrawal symptoms after running out of study medication. The patient had not reported withdrawal symptoms during scheduled respites from doses of 30 or 40 mg/d." (3) "Withdrawal syndrome was not reported as an adverse event for any patient during scheduled respites. Adverse experiences reported by more than 10% of patients during scheduled respites were nervousness (9 patients) and insomnia (8 patients)."

32. The osteoarthritis study article also included a "Comment" section. The statement regarding withdrawal in this section largely summarized the information in the three statements in the "Results" section and further suggested that patients taking low doses could have their OxyContin treatment abruptly discontinued without experiencing withdrawal if their condition so warranted: "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites, indicating that [OxyContin] at doses below 60 mg [per day] can be discontinued without tapering the dose if the patient's condition so warrants."

33. On or about May 18, 2000, after millions of OxyContin tablets had been sold and used by patients, PURDUE's Medical Services Department reported to certain PURDUE supervisors and

employees that it had recently received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms and the report indicated that "this type of question, patients not being able to stop OxyContin without withdrawal symptoms has come up quite a bit here in Medical Services lately (at least 3 calls in the last 2 days)."

34. On or about June 26, 2000, certain PURDUE supervisors and employees sent the full text of the osteoarthritis study article together with a "marketing tip" to PURDUE's entire sales force. The marketing tip stated that a reprint of the osteoarthritis study article was available for use in achieving sales success. The marketing tip also included as one of the article's twelve key points: "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d can be discontinued without tapering the dose if the patient condition so warrants."

35. On or about February 13, 2001, certain PURDUE supervisors and employees received a review of the accuracy of the withdrawal data in the osteoarthritis study that stated: "Upon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms." This was followed by a list of eleven study patients who reported adverse experience due to possible withdrawal symptoms during these periods. 106 patients initially participated in the osteoarthritis study, 32 of them withdrew because of adverse events (not necessarily related to withdrawal), and 38 patients remained in the study at 12 months.

36. On or about March 28, 2001, a PURDUE employee emailed a PURDUE supervisor regarding the review of withdrawal data described in paragraph 35 of this Agreed Statement of Facts,

asking: "Do you think the withdrawal data from the [osteoarthritis] study . . . is worth writing up (an abstract)? Or would this add to the current negative press and should be deferred?" The supervisor responded: "I would not write it up at this point." No abstract was prepared.

37. Between approximately June 26, 2000, and June 30, 2001, certain PURDUE supervisors and employees distributed copies of the reprint of the osteoarthritis study article to all of PURDUE's sales representatives for use in the promotion and marketing of OxyContin to health care providers, including the distribution of 10,615 copies to certain PURDUE sales representatives between February 13, 2001, and June 30, 2001.

38. During the period June 26, 2000, through June 30, 2001, certain PURDUE sales representatives distributed the reprint of the osteoarthritis study article to some health care providers and falsely or misleadingly stated that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms and that patients on such doses would not develop tolerance.

Misbranding of OxyContin: Use of Reduced Abuse Liability Claim in Marketing

39. The original OxyContin package insert approved by the FDA stated: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug" (the *Reduced Abuse Liability Statement*). Certain PURDUE supervisors and employees instructed PURDUE sales representatives to use this statement to market and promote OxyContin.

40. Certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used

to "weed out" addicts and drug seekers.

41. By March 2000, various PURDUE supervisors and employees in different parts of the company had received reports of OxyContin abuse and diversion occurring in different communities.

42. On or about November 27, 2000, certain PURDUE supervisors and employees amended the *Reduced Abuse Liability Statement* to state that "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug," and instructed PURDUE sales representatives to use the amended statement to promote and market OxyContin.

43. From March 2000 through June 30, 2001, certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* and the amended statement meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

Introduction of Misbranded OxyContin Into Interstate Commerce

44. In or about and between January 1996 and June 30, 2001, PURDUE manufactured, marketed, and sold quantities of OxyContin in interstate commerce from various locations outside the state of Virginia to various locations in the Western District of Virginia and elsewhere, which were misbranded within the meaning of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(a), as described in paragraphs 19 through 43 of this Agreed Statement of Facts.

45. Between in or about January 1996 and on or about June 30, 2001, defendants MICHAEL FRIEDMAN, HOWARD R. UDELL, and PAUL D. GOLDENHEIM, were responsible

corporate officers of PURDUE under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a).

46. Defendants MICHAEL FRIEDMAN, HOWARD R. UDELL, and PAUL D. GOLDENHEIM ("individual defendants") do not agree that they had personal knowledge of all of the matters set forth in paragraphs 1 through 44 of this Agreed Statement of Facts. However, they agree that the Court may accept these facts, as agreed to by defendant THE PURDUE FREDERICK COMPANY, INC., as part of the factual basis supporting the guilty pleas by the individual defendants.

The parties agree to the foregoing Agreed Statement of Facts.

Date: May 9, 2007

FOR THE UNITED STATES:

John L. Brownlee

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

FOR DEFENDANT THE PURDUE FREDERICK COMPANY, INC.:

Date: May 7, 2007

Robin E. Abrams, Esquire
Vice-President and Director of
The Purdue Frederick Company, Inc. and
Vice-President and Associate General Counsel
of Purdue Pharma L.P.
Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

Date: May 8, 2007

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

FOR DEFENDANT MICHAEL FRIEDMAN:

Date: May 7, 2007

Michael Friedman, Defendant

Date: _____

Mark D. Pomerantz, Esquire
Counsel for Michael Friedman

FOR DEFENDANT HOWARD R. UDELL:

Date: May 7, 2007

Howard R. Udell, Defendant

Date: _____

Mary Jo White, Esquire
Counsel for Howard R. Udell

FOR DEFENDANT PAUL D. GOLDENHEIM:

Date: _____

Paul D. Goldenheim, Defendant

Date: _____

Andrew Good, Esquire
Counsel for Paul D. Goldenheim

FOR DEFENDANT THE PURDUE FREDERICK COMPANY, INC.:

Date: _____

Robin E. Abrams, Esquire
Vice-President and Director of
The Purdue Frederick Company, Inc. and
Vice-President and Associate General Counsel
of Purdue Pharma L.P.
Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

Date: _____

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

FOR DEFENDANT MICHAEL FRIEDMAN:

Date: 5/7/07

Michael Friedman, Defendant

Date: 5/8/07

Mark F. Pomerantz, Esquire
Counsel for Michael Friedman

FOR DEFENDANT HOWARD R. UDELL:

Date: _____

Howard R. Udell, Defendant

Date: _____

Mary Jo White, Esquire
Counsel for Howard R. Udell

FOR DEFENDANT PAUL D. GOLDENHEIM:

Date: _____

Paul D. Goldenheim, Defendant

Date: _____

Andrew Good, Esquire
Counsel for Paul D. Goldenheim

FOR DEFENDANT THE PURDUE FREDERICK COMPANY, INC.:

Date: _____

_____

Robin E. Abrams, Esquire
Vice-President and Director of
The Purdue Frederick Company, Inc. and
Vice-President and Associate General Counsel
of Purdue Pharma L.P.
Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

Date: _____

_____

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

FOR DEFENDANT MICHAEL FRIEDMAN:

Date: _____

_____

Michael Friedman, Defendant

Date: _____

_____

Mark D. Pomerantz, Esquire
Counsel for Michael Friedman

FOR DEFENDANT HOWARD R. UDELL:

Date: 5/7/07

Howard R. Udell

Howard R. Udell, Defendant

Date: 5/8/07

Mary Jo White

Mary Jo White, Esquire
Counsel for Howard R. Udell

FOR DEFENDANT PAUL D. GOLDENHEIM:

Date: _____

_____

Paul D. Goldenheim, Defendant

Date: _____

_____

Andrew Good, Esquire
Counsel for Paul D. Goldenheim

FOR DEFENDANT THE PURDUE FREDERICK COMPANY, INC.:

Date: _____

Robin E. Abrams, Esquire
Vice-President and Director of
The Purdue Frederick Company, Inc. and
Vice-President and Associate General Counsel
of Purdue Pharma L.P.
Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

Date: _____

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

FOR DEFENDANT MICHAEL FRIEDMAN:

Date: _____

Michael Friedman, Defendant

Date: _____

Mark D. Pomerantz, Esquire
Counsel for Michael Friedman

FOR DEFENDANT HOWARD R. UDELL:

Date: _____

Howard R. Udell, Defendant

Date: _____

Mary Jo White, Esquire
Counsel for Howard R. Udell

FOR DEFENDANT PAUL D. GOLDENHEIM:

Date: May 8, 2007

Paul D. Goldenheim, Defendant

Date: May 8, 2007

Andrew Good, Esquire
Counsel for Paul D. Goldenheim

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Case No.** _____
	)	
THE PURDUE FREDERICK COMPANY, INC.	)	

PLEA AGREEMENT

THE PURDUE FREDERICK COMPANY, INC. ("PURDUE") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this agreement are as follows:

1. CHARGE TO WHICH PURDUE IS PLEADING GUILTY AND WAIVER OF RIGHTS

PURDUE will enter a plea of guilty to Count One of an Information, charging it with the felony of misbranding a drug, with the intent to defraud or mislead, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2). The maximum statutory penalty is a fine of $500,000.00 or twice the gross gain or loss, pursuant to Title 18, United States Code, Sections 3571(c)(3) and 3571(d), plus a period of probation of up to five years, pursuant to Title 18, United States Code, Section 3561(c)(1). In addition, PURDUE's assets may be subject to forfeiture. PURDUE understands that fees may be imposed to pay for probation and that there will be a $400 special assessment, pursuant to Title 18, United States Code, Section 3013(a)(2)(B). PURDUE's attorney has informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before PURDUE could be found guilty as charged.

PURDUE hereby waives its right to be proceeded against by indictment and consents to the filing of an Information charging it with a violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

PURDUE acknowledges that PURDUE has had all of its rights explained to it. PURDUE expressly recognizes that, as a corporation, PURDUE may have the following constitutional rights and, that by voluntarily pleading guilty, PURDUE knowingly waives and gives up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.

The right to confront and cross-examine witnesses.
The right to present evidence and witnesses.
The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

PURDUE is pleading guilty as described above because PURDUE is in fact guilty and because PURDUE believes it is in its best interest to do so and not because of any threats or promises, other than the terms of the Plea Agreement, described herein, in exchange for its plea of guilty. PURDUE agrees that all of the matters set forth in the Information are true and correct.

PURDUE understands that the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree and stipulate that the 2006 United States Sentencing Guidelines ("U.S.S.G.") Manual should be used and the following sentencing guidelines sections apply, exclusively.

The Offense Level is computed as follows:

6	§ 2B1.1(a)(2)	Base offense level (cross reference from §2N2.1(b)(1)).
+2	§ 2B1.1(b)(2)(A)(ii)	The offense was committed through mass-marketing.
+2	§ 2B1.1(b)(9)(C)	The offense involved sophisticated means.
10	Total	
12	§ 2B1.1(b)(9)	If the resulting offense level is less than level 12, increase to level 12.

Total Offense Level is 12

The Culpability Score is computed as follows:

5	§ 8C2.5(a)	Start with 5 points.
+4	§ 8C2.5(b)(2)(A)(ii)	The organization had 1,000 or more employees.
- 1	§ 8C2.5(g)(3)	The organization accepted responsibility for its criminal conduct.

Total Culpability Score is 8.

The Base Fine for an Offense Level of 12 is $40,000.00 (§ 8C2.4(d)).

The Minimum Multiplier for a Culpability Score of 8 is 1.60 (§ 8C2.6).
The Maximum Multiplier for a Culpability Score of 8 is 3.20 (§ 8C2.6).

The Guideline Fine Range is $64,000.00 to $128,000.00 ((1.60 x $40,000.00) to (3.20 x $40,000.00)) (§ 8C2.7).

The United States asserts that an upward departure to a statutory maximum fine of $500,000.00 is appropriate because, pursuant to § 5K2.0(a)(1)(A), there exists an aggravating circumstance of a kind, or to a degree, not adequately taken into consideration by the Sentencing Commission in formulating the guidelines. PURDUE does not oppose the Court ordering the statutory maximum fine of $500,000.00.

The parties agree and stipulate that determining the pecuniary gain or loss would unduly complicate or prolong the sentencing process and, in accordance with U.S.S.G. § 8C2.4(c) and 18 U.S.C. § 3571(d), should not be used for the determination of the fine.

The parties agree that if the Court refuses to accept the Plea Agreement with the agreed-upon sentence, this Plea Agreement will be null and void, and PURDUE will be free to withdraw this guilty plea. In the event the Court refuses to accept the Plea Agreement with the agreed-upon sentence and PURDUE withdraws this guilty plea, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410 and the United States will move to dismiss the Information without prejudice to the United States' right to indict PURDUE or any other entity or individual on any charge.

The parties have not agreed to any matters concerning the length and terms of probation. Accordingly, the Court may impose whatever length and terms of probation, if any, that it determines is appropriate.

3. FINANCIAL OBLIGATIONS

PURDUE agrees and understands that any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept the Plea Agreement with the agreed-upon sentence and, as a result, PURDUE withdraws its guilty plea.

For the remaining portions of this "FINANCIAL OBLIGATIONS" section, "PURDUE" means "THE PURDUE FREDERICK COMPANY, INC. or Purdue Pharma L.P.")

a. Immediate Payments

Prior to the entry of PURDUE's guilty plea, PURDUE will make the following disbursements:

(1) $3,087,277.60 (three million eighty-seven thousand two hundred seventy-seven dollars and sixty cents) to the Federal and State Medicaid programs for improperly calculated Medicaid rebates for the years 1998 and 1999;

(2) $500,000.00 (five hundred thousand dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the maximum statutory fine;

(3) $20,000,000.00 (twenty million dollars) will be paid into an account to be held in trust ("Trust Account") solely for the operation of the Virginia Prescription Monitoring Program ("PMP") or its successors. The Trust Account funds should be prudently invested to ensure an adequate return. Money may be drawn from the Trust Account solely for the purpose of funding the PMP (including, but not limited to, operating and maintaining the PMP and providing training and educational programs concerning the use of the PMP.) The maximum amount to be drawn from the account each year shall be the lesser of (a) sufficient funds to fund Virginia's Prescription Monitoring Program or (b) the Yearly Expenditure Cap. The Yearly Expenditure Cap will be $1,000,000.00 (one million dollars) for the first year and will increase by 4% per year. If, prior to December 31, 2057, there is a calendar year during which Virginia does not have a PMP or its rough equivalent, the remaining money in the Trust Account shall be paid to the United States Treasury. The money in the Trust Account may not be used for any purpose other than funding the PMP, prior to December 31, 2057. As of December 31, 2057, if the PMP and its successors no longer exist, the money remaining in the account may be used for any purpose, for the benefit of the Commonwealth of Virginia;

(4) $5,300,000.00 (five million three hundred thousand dollars) to the Virginia Medicaid Fraud Control Unit's Program Income Fund; and

(5) $151,100,000.00 (one hundred fifty-one million one hundred thousand dollars) as directed by the United States Attorney's Office as partial payment of a total forfeiture of $276,100,000.00 (two hundred seventy six million one hundred thousand dollars).

b. Civil Settlement Payments

PURDUE will pay a total of $160,000,000.00 (one hundred sixty million dollars) to the United States and the States to settle civil governmental claims, as set forth below:

(1) PURDUE shall pay $100,615,797.25 (one hundred million six hundred fifteen thousand seven hundred ninety-seven dollars and twenty-five cents) to the United States plus interest at the rate of 4.75% per annum ($13,093.84 per day) on $100,615,797.25 from the

date of the plea by The Purdue Frederick Company, Inc. and continuing until and including the day before complete payment is made pursuant to the Civil Settlement Agreement (attached as Attachment D) between the United States and PURDUE; and $59,384,202.75 (fifty-nine million three hundred eighty-four thousand two hundred two dollars and seventy-five cents) to the States as set forth in Section 3(b)(2) below. These payments shall satisfy Purdue's obligation to make restitution under this Plea Agreement;

(2) The $59,384,202.75 paid to the States shall be placed in a dedicated interest bearing account. Each state that elects to participate in this settlement shall, upon execution of the Form State Release (attached as Attachment L) (or an alternative release agreed to by PURDUE and the state), receive its proportionate share as determined by the Medicaid Fraud Control Unit Negotiating Team, plus interest in accordance with the Form State Release, in a timely manner in accordance with the schedule as provided in the Form State Release. Any money remaining in the dedicated interest bearing account after PURDUE has fully paid all of its obligations shall be returned to PURDUE; and

(3) The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no other restitution should be ordered.

c. Subsequent Forfeiture Payments

On or before the six month anniversary of the entry of its guilty plea, PURDUE will deposit $90,000,000.00 (ninety million dollars) as directed by the United States Attorney's Office as payment toward a total forfeiture of $276,100,000.00 (two hundred seventy six million one hundred thousand dollars).

On or before the twelve month anniversary of the entry of its guilty plea, PURDUE will deposit $35,000,000.00 (thirty-five million dollars) as directed by the United States Attorney's Office as final payment of a total forfeiture of $276,100,000.00 (two hundred seventy six million one hundred thousand dollars).

d. Compensation and Settlement

Based on the agreement in principle reached between PURDUE and the United States on October 25, 2006, PURDUE set aside a total of $130,000,000.00 (one hundred thirty million dollars), some or all of which will have been paid by the date of the entry of the guilty plea, for compensation and settlement of private civil liabilities related to OxyContin. Any of the $130,000,000.00 (one hundred thirty million dollars) remaining unpaid two years after the entry of

PURDUE's guilty plea will be paid to the United States Treasury. Two years after the entry of PURDUE's guilty plea or at the time the entire $130,000,000.00 has been appropriately expended (if the moneys have been expended in less than two years), PURDUE's attorney shall provide to the Court and the United States Attorney's Office an accounting of the moneys paid and will certify that all payments have been made to resolve PURDUE's private civil liabilities related to OxyContin.

e. Forfeiture

To accomplish the forfeiture, which will be paid as set forth above, PURDUE agrees to the filing of a civil forfeiture complaint, pursuant to 18 U.S.C. § 981(a)(1)(A), in the Western District of Virginia and agrees to forfeit $276,100,000.00 in cash in settlement of the forfeiture complaint ("settlement sum"). PURDUE agrees to sign, concurrent with the signing of this Plea Agreement, a settlement agreement acknowledging that the settlement sum represents proceeds of a violation of 18 U.S.C. § 1957 and/or are forfeitable in lieu of certain property that would be otherwise subject to forfeiture pursuant to 19 U.S.C. § 1613(c). PURDUE agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of this sum to the United States. These steps include but are not limited to making the sum available to the United States, as directed by the United States. PURDUE agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. PURDUE understands and agrees that forfeiture of this property is proportionate to the degree and nature of the offense, and does not raise any of the concerns raised in *United States v. Austin*, 113 S.Ct. 2801 (1993). To the extent that such concerns are raised, PURDUE freely and knowingly waives any and all right it may have to raise a defense of "excessive fines" under the Eighth Amendment to this forfeiture. PURDUE further understands and agrees that this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty that may be imposed by the court.

f. Monitoring Costs

PURDUE agrees to expend not less than $5,012,722.40 (five million twelve thousand seven hundred twenty-two dollars and forty cents) in monitoring costs over the next seventy-two months for the purpose of ensuring that Purdue Pharma L.P. complies with its Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services Office of Inspector General ("OIG") and does not engage in any further criminal activity. On an annual basis, beginning on the first anniversary of PURDUE's guilty plea, PURDUE's attorney shall provide to the United States Attorney's Office an accounting of the moneys paid and will certify that all payments set forth therein have been paid as part of a monitoring program as set forth by the CIA between Purdue Pharma L.P. and the OIG or otherwise to prevent future criminal activity by Purdue Pharma L.P. Any of the $5,012,722.40 (five million twelve thousand seven hundred twenty-two dollars and forty cents) remaining unspent seventy-two months after the entry of PURDUE's guilty plea will be paid to the United States Treasury.

g. **Security**

Prior to pleading guilty, Purdue agrees to provide a lien to the United States against sufficient company assets to secure the $125,000,000.00 in deferred payments.

4. MANDATORY ASSESSMENT

PURDUE understands that there is a mandatory assessment of $400.00 per felony count of conviction. PURDUE agrees that it will submit to the U.S. Clerk's Office, a certified check, money order, or attorney's trust check, made payable to the "Clerk, U.S. District Court" in the amount of $400.00 within seven days of entering its plea of guilty.

5. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, PURDUE withdraws its plea, PURDUE agrees to: (1) accept responsibility for its conduct; (2) fully comply with all terms of probation, if probation is imposed; (3) not attempt to withdraw its guilty plea; (4) not deny that it committed the crime to which it has pled guilty; and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement (if a presentence report is ordered by the Court); and (6) comply with its obligations under the Civil Settlement Agreement (attached as Attachment D).

PURDUE consents to public disclosure of all resolution documents related to this case.

Neither PURDUE nor any of its associated entities (as set forth in Attachment A), will, through its present or future directors, officers, employees, agents, or attorneys, make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in the Agreed Statement of Facts (attached as Attachment B). Should the United States Attorney's Office for the Western District of Virginia notify PURDUE of a public statement by any such person that in whole or in part contradicts a statement of fact contained in the Agreed Statement of Facts, PURDUE may avoid noncompliance with its obligations under this Plea Agreement by publicly repudiating such statement within two business days after such notification. Notwithstanding the above, any PURDUE entity may avail itself of any legal or factual arguments available to it in defending litigation brought by a party other than the United States or in any investigation or proceeding brought by a state entity or by the United States Congress. This paragraph is not intended to apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative or civil case initiated by any governmental or private party against such individual.

6. ADMISSIBILITY OF STATEMENTS

PURDUE understands that any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against

it in this or any other related criminal proceeding. PURDUE knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other related criminal proceeding. With the exception of the situations set forth above, PURDUE does not waive its right to argue against admissibility under any ground permitted under federal or state rules of evidence in any other proceeding.

If the Court rejects the Plea Agreement, and, as a result, PURDUE withdraws its plea, PURDUE will not be bound by the waivers set forth in this section of the Plea Agreement.

7. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, PURDUE agrees that PURDUE will not appeal the conviction or sentence imposed. PURDUE is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C).

PURDUE agrees not to collaterally attack the judgment and/or sentence imposed in this case and waives its right, if any, to collaterally attack, pursuant to Title 28, United States Code, Section 2255, the judgment and any part of the sentence imposed upon it by the Court. PURDUE agrees and understands that if PURDUE, or anyone acting on PURDUE's behalf, files any court document (including but not limited to a notice of appeal) seeking to disturb, in any way, the judgment and/or sentence imposed in its case, the United States will be free to take whatever actions it wishes based on this failure of PURDUE to comply with its obligations under the Plea Agreement.

8. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION

PURDUE understands that if: (1) PURDUE attempts to withdraw its plea (in the absence of the Court refusing to accept the Plea Agreement) or fails to comply with any provision of this Plea Agreement, at any time; (2) any defendant in this case does not fulfill the defendant's obligations under the defendant's plea agreement prior to the imposition of judgment; (3) PURDUE's conviction is set aside, for any reason; (4) any entity related to any defendant fails to execute all required paperwork or fails to fulfill its obligations to effectuate the resolution of this entire investigation prior to the imposition of judgment; and/or (5) PURDUE fails to comply with its obligations under the Civil Settlement Agreement (attached as Attachment D) the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement entitled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, PURDUE will still be bound by its obligations under this Plea Agreement. PURDUE hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of the Plea Agreement. PURDUE hereby waives any statute of limitations argument as to any such charges.

9. INFORMATION ACCESS WAIVER

PURDUE and any related entity knowingly and voluntarily agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

10. DESTRUCTION OF ITEMS OBTAINED BY LAW ENFORCEMENT

By signing this Plea Agreement, PURDUE and any related entities hereby consent to the destruction of all items obtained by law enforcement agents during the course of the investigation, with the exception of the company's original files. However, PURDUE expressly agrees that, within 30 days of being informed by the United States Attorney's Office that records and/or other items obtained from PURDUE or entities/individuals who were employed by PURDUE or entities/individuals who were agents of PURDUE are available for removal, it will remove, at its cost, all such records and/or other items from the premises designated by the United States Attorney's Office.

11. COMPLETION OF PROSECUTION

PURDUE understands that except as provided for in this Plea Agreement and the Non-Prosecution Agreement (attached as Attachment C), so long as PURDUE complies with all of its obligations under the Plea Agreement, and all entities set forth in the Non-Prosecution Agreement comply with their obligations therein, there will be no further criminal prosecution or forfeiture action by the United States for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement, against the following, or any property owned by any of the following: PURDUE, its current and former directors, officers, employees, co-promoters, owners (including trustees and trust beneficiaries of such owners), successors and assigns; any of PURDUE'S related and associated entities (as listed on Attachment A); and such related and associated entities' current and former directors, officers, employees, owners (including trustees and trust beneficiaries of such owners), successors and assigns, and trusts for the benefit of the families of the current and former directors of PURDUE, including the trustees and trust beneficiaries of such trusts.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

PURDUE understands that nothing in this Plea Agreement precludes any private party from pursuing any civil remedy against PURDUE, and PURDUE agrees that it will not raise this Plea Agreement or its guilty plea as a defense to any such civil action.

12. LIMITATION OF AGREEMENT

This Plea Agreement is limited to the United States of America and does not bind any state or local authorities.

13. EFFECTIVE REPRESENTATION

PURDUE has discussed the terms of the foregoing Plea Agreement and all matters pertaining to the charges against it with its attorney and is fully satisfied with its attorney and its attorney's advice. At this time, PURDUE has no dissatisfaction or complaint with its attorney's representation. PURDUE agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint PURDUE may have with its attorney's representation.

14. EFFECT OF PURDUE'S SIGNATURE

PURDUE understands that its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. PURDUE understands that the United States has not accepted PURDUE's offer until the authorized representative of the United States has signed the Plea Agreement.

15. GENERAL UNDERSTANDINGS

The parties jointly submit that this Plea Agreement and the Agreed Statement of Facts provide sufficient information concerning PURDUE and the crimes charged in this case to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. The parties agree to request that the Court impose sentence at the date of the arraignment and plea pursuant to the provisions of Fed. Rule Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1(a)(2), if the Court determines that a presentence report is not necessary.

If the Court orders a presentence report, PURDUE understands that a thorough presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

PURDUE understands that the prosecution will be free to allocute or describe the nature of this offense and the evidence in this case.

PURDUE understands that the United States retains the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address

the Court with respect to the nature and seriousness of the offense(s), to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court by or on behalf of the defendant.

PURDUE willingly stipulates that there is a sufficient factual basis for the Court to accept the plea.

PURDUE understands that this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

PURDUE has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. PURDUE understands that its attorney will be free to argue any mitigating factors on its behalf; to the extent they are not inconsistent with the terms of this Plea Agreement. PURDUE understands that PURDUE will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing and the Agreed Statement of Facts (attached as Attachment B), Non-Prosecution Agreement (attached as Attachment C), Civil Settlement Agreement (attached as Attachment D), Corporate Integrity Agreement (attached as Attachment E), Stipulation for Compromise Settlement (attached as Attachment G), and Agreed Order of Forfeiture (attached as Attachment H) are the complete and only agreements between the United States and PURDUE, Purdue Pharma L.P. and its related and associated entities concerning resolution of this matter. Also attached to this agreement are the Virginia Release (attached as Attachment L) and the Form State Release (attached as Attachment M). In addition, PURDUE has no objection to the filing of the Information (Attachment F), Verified Complaint for Forfeiture *In Rem* (attached as Attachment I), and the Notice of Compliance (attached as Attachment J) and the Court's entry of a Warrant of Arrest *In Rem* (attached as Attachment K). The agreements and documents listed in this paragraph set forth the entire understanding between the parties and constitutes the complete agreement between the United States Attorney for the Western District of Virginia and PURDUE, Purdue Pharma L.P. and its related and associated entities and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and PURDUE, Purdue Pharma L.P. and its related and associated entities.

PURDUE has consulted with its attorney and fully understands its rights with respect to the offenses charged in the charging document(s). Further, PURDUE has consulted with its attorney and fully understands its rights. PURDUE has read this Plea Agreement and carefully reviewed every part of it with its attorney. PURDUE understands this Plea Agreement and PURDUE voluntarily agrees to it. Being aware of all of the possible consequences of its plea, PURDUE has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer below.

The Authorized Corporate Officer, by her signature below, hereby certifies to the following:

(1) She has read the entire Plea Agreement and documents referenced herein and discussed them with PURDUE's owners;

(2) PURDUE understands all the terms of the Plea Agreement and those terms correctly reflect the results of plea negotiations;

(3) PURDUE is fully satisfied with PURDUE's attorneys' representation during all phases of this case;

(4) PURDUE is freely and voluntarily pleading guilty in this case;.

(5) PURDUE is pleading guilty as set forth in this Plea Agreement because it is guilty of the crimes to which it is entering its plea; and

(6) PURDUE understands that it is waiving its right to appeal the judgment and conviction in this case.

PURDUE acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Authorized Corporate Officer. A copy of a certification by PURDUE's Board of Directors authorizing the Authorized Corporate Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of PURDUE is attached.

Date: May 7, 2007

Robin E. Abrams

Robin E. Abrams, Esquire
Vice-President and Director of
The Purdue Frederick Company, Inc. and
Vice-President and Associate General Counsel
of Purdue Pharma L.P.
Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

I have discussed with and fully explained to the Board of Directors of PURDUE the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the Sentencing Guidelines; and all of the consequences of entering into this Plea Agreement and entering a guilty plea. I have reviewed the entire Plea Agreement and documents referenced herein with my client, through its Authorized Corporate Officer. In my judgment, PURDUE understands the terms and conditions of the Plea Agreement, and I believe PURDUE's decision to enter into the Plea Agreement is knowing and voluntary. PURDUE's execution of and entry into the Plea Agreement is done with my consent.

Date: May 8, 2007

Howard M. Shapiro

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

Date: May 9, 2007

John L. Brownlee

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

SCHEDULE 1

RESOLVED, that the Agreed Statement of Facts between the United States of America and the Corporation (the "Agreed Statement of Facts") in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that the Settlement Agreement among the United States of America, acting through the Civil Division of the Department of Justice and the United States Attorney's Office for the Western District of Virginia, the Office of the Inspector General of the United States Department of Health and Human Services, the United States Office of Personnel Management, the United States Department of Defense TRICARE Management Activity, the United States Department of Labor Office of Workers' Compensation Programs, the Corporation and Purdue Pharma L.P., a Delaware limited partnership (the "Civil Settlement Agreement"), in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that the Plea Agreement between the United States of America and the Corporation (the "Plea Agreement") in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that the Stipulation for Compromise Settlement between the United States of America and the Corporation (the "Stipulation for Compromise Settlement") in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that the Agreed Order of Forfeiture between the United States of America and the Corporation (the "Agreed Order of Forfeiture"; the Agreed Statement of Facts, the Civil Settlement Agreement, the Plea Agreement, the Stipulation for Compromise Settlement, and the Agreed Order of Forfeiture are hereinafter collectively referred to as the "Settlement Documents"), in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that Robin E. Abrams as the Vice President of the Corporation, be and she hereby is authorized and directed to execute and deliver in the name and on behalf of the Corporation the Settlement Documents, each in the form or substantially in the form presented to the Director of the Corporation, with such changes, additions and modifications thereto as she shall approve, such approval to be conclusively evidenced by her execution and delivery thereof; and further

RESOLVED, that Robin E. Abrams as the Vice President of the Corporation, be and she hereby is authorized and directed to make, execute and deliver, or cause to be made, executed and delivered, all such agreements, documents, instruments and other papers, and to do or cause to be done on behalf of the Corporation all such acts, as she may deem necessary or appropriate to carry out the purposes and intent of the foregoing resolutions, including, but not limited to, appearing on behalf of the Corporation in the United States District Court for the Western district of Virginia, Abingdon Division, in order to make any statement or statements on behalf of the Corporation she deems appropriate in connection with the judgment to be pronounced against the Corporation in accordance with the Settlement Documents.

THE PURDUE FREDERICK COMPANY INC.

Vice President's Certificate

The undersigned, Robin E. Abrams, the Vice President of The Purdue Frederick Company Inc., a New York corporation (the "Corporation"), DOES HEREBY CERTIFY that attached hereto as Schedule 1 is a true, correct and complete copy of the resolutions approved by the Written Consent of the Sole Director of the Corporation dated May 4, 2007 authorizing the Corporation to execute and deliver on behalf of the Corporation that certain Plea Agreement between the United States of America and the Corporation, together with other documents listed therein with respect to settling that certain investigation by the United States Attorney's Office for the Western District of Virginia, which resolutions have not been amended or rescinded as of the date hereof.

IN WITNESS WHEREOF, the undersigned has executed this Certificate this May 4, 2007.

Robin E. Abrams
Vice President

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Case No.** _____
	)	
MICHAEL FRIEDMAN	)	

PLEA AGREEMENT

My counsel and I have entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P.)" The terms and conditions of this agreement are as follows:

1. CHARGE(S) TO WHICH I AM PLEADING GUILTY AND WAIVER OF RIGHTS

I will enter a plea of guilty to Count Two of the attached Information, charging me with the strict liability misdemeanor offense of misbranding a drug in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1). The maximum statutory penalty for Count Two is a fine of $100,000.00, pursuant to 18 U.S.C. § 3571(b)(5), and/or imprisonment for a term of one year, plus a period of supervised release. I understand that fees may be imposed to pay for incarceration or supervised release and that there will be a $25 special assessment, pursuant to 18 U.S.C. § 3013(a)(1)(A)(iii). I further understand that any term of probation may be revoked if I violate its terms and conditions.

My attorney has informed me of the nature of the charge(s) and the elements of the charge(s) that must be proved by the United States beyond a reasonable doubt before I could be found guilty as charged.

I acknowledge that I have had all of my rights explained to me and I expressly recognize that I have the following constitutional rights and, that by voluntarily pleading guilty, I knowingly waive and give up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses in my own behalf.
The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

Defendant's Initials: MF

I am pleading guilty as described above because I am in fact guilty and because I believe it is in my best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for my plea of guilty. I agree that the Court can accept the Agreed Statement of Facts as the factual basis for my guilty plea.

I understand that the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree and stipulate that the following Guidelines' section should apply, exclusively, to my conduct:

2N2.1	6	Base Offense Level

Pursuant to Fed. R. Crim. P. 11(c)(1)(C), the parties agree to ask the Court to impose a non-incarcerative sentence. The parties agree that if the Court refuses to accept the Plea Agreement with the agreed-upon sentence I will be free to withdraw this guilty plea. In that event, this Agreement will be null and void and nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410 and the United States will move to dismiss the Information without prejudice to the United States' right to indict me or any other entity or individual on any charge.

The parties agree and stipulate that restitution is not applicable to my conviction.

If the Court were to impose a sentence that includes probation, I do not believe that any non-standard conditions of probation are appropriate. The United States agrees to take no position as to any non-standard conditions of probation.

3. DISGORGEMENT

Prior to the entry of my guilty plea, I will transfer $19,000,000.00 (nineteen million dollars) to the Virginia Medicaid Fraud Control Unit's Program Income Fund. If the Court rejects this Plea Agreement and, as a result, I withdraw my plea, the $19,000,000.00 (nineteen million dollars) will be returned to me.

4. MANDATORY ASSESSMENT AND FINE

I understand that there is a mandatory assessment of $25.00 per misdemeanor count of conviction. The parties agree and stipulate that a fine of $5,000.00, at the upper end of the guidelines' range, is appropriate for this case. I agree that I will submit to the U.S. Clerk's Office, a certified check, money order, or attorney's trust check, made payable to the "Clerk, U.S. District Court" in the amount of $5,025.00 within seven days of entering my plea of guilty.

5. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, I withdraw my plea, I agree to: (1) accept responsibility for my conduct; (2) fully comply with all terms of probation, if a term of probation is imposed; (3) not attempt to withdraw my guilty plea; (4) not deny that I committed the crime to which I have pled guilty; and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this agreement (if a presentence report is ordered by the Court).

I consent to public disclosure of all resolution documents related to this case.

I will not make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in the Agreed Statement of Facts. Should the United States Attorney's Office for the Western District of Virginia notify me of a public statement that contradicts a statement of fact contained in the Agreed Statement of Facts, I may avoid noncompliance with my obligations under this Plea Agreement by publicly repudiating such statement within two business days after such notification. Notwithstanding the above, I may avail myself of any legal or factual arguments available to me in defending litigation brought by a party other than the United States or in any investigation or proceeding brought by a state entity or by the United States Congress. This paragraph is not intended to apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative or civil case initiated by any governmental or private party against such individual.

6. ADMISSIBILITY OF STATEMENTS

I understand that any statements I make or made on my behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against me in this or any other related criminal proceeding. I knowingly waive any right I may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other related criminal proceeding. With the exception of the situations set forth above, I do not waive my right to argue against admissibility under any ground permitted under federal or state rules of evidence in any other proceeding.

If the Court rejects the Plea Agreement, and, as a result, I withdraw my plea, I will not be bound by the waivers set forth in this section of the Plea Agreement.

7. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, I agree that I will not appeal the conviction or sentence imposed. I am knowingly and voluntarily waiving any right to appeal and am voluntarily willing to rely on the Court in sentencing me pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). I agree not to collaterally attack the judgment and/or sentence imposed in this case and waive my right to collaterally attack, pursuant to Title 28, United States Code, Section 2255, the judgment and

any part of the sentence imposed upon me by the Court. I agree and understand that if I file any court document (including but not limited to a notice of appeal) seeking to disturb, in any way, the judgment and/or sentence imposed in my case, the United States will be free to take whatever actions it wishes based on this failure to comply with my obligations under the Plea Agreement.

8. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION

I understand that if: (1) I attempt to withdraw my plea (in the absence of the Court refusing to accept the Plea Agreement) or fail to comply with any provision of this agreement, at any time; (2) any defendant in this case does not fulfill the defendant's obligations under the defendant's Plea Agreement prior to the imposition of judgment; (3) my conviction is set aside, for any reason; and/or (4) any entity related to any defendant fails to execute all required paperwork or fails to fulfill its obligations to effectuate the resolution of this entire investigation prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this agreement, including, but not limited to, those obligations set forth in the section of this agreement entitled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this agreement, I will still be bound by my obligations under this agreement. I hereby waive my right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consent to the filing of an information against me concerning any charges filed pursuant to this section of the Plea Agreement. I hereby waive any statute of limitations argument as to any such charges.

9. INFORMATION ACCESS WAIVER

I knowingly and voluntarily agree to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. §552, or the Privacy Act of 1974, 5 U.S.C. §552a.

10. DESTRUCTION OF ITEMS OBTAINED BY LAW ENFORCEMENT

The United States Attorney's Office will inform me when my personal financial records and/or other records or items obtained from my accountant or any documents otherwise relating to my personal finances are available for removal. I expressly agree that, within 30 days of being informed by the United States Attorney's Office that such records are available for removal, I will remove, at my cost, all such records from the premises designated by the United States Attorney's

Office. In addition, by signing this Plea Agreement, I hereby consent to the destruction of all items obtained by law enforcement agents during the course of the investigation (other than those described above), and will execute any documents necessary to comply with this provision.

11. COMPLETION OF PROSECUTION

I understand that except as provided for in this agreement, so long as I comply with all of my obligations under the agreement, there will be no further criminal prosecution or forfeiture action by the United States against me, for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

I understand that nothing in this Plea Agreement precludes any private party from pursuing any civil remedy against me, and I agree that I will not raise this Plea Agreement or my guilty plea as a defense to any such civil action.

12. LIMITATION OF AGREEMENT

This Plea Agreement is limited to the United States of America and does not bind any state or local authorities.

13. EFFECTIVE REPRESENTATION

I have discussed the terms of the foregoing Plea Agreement and all matters pertaining to the charges against me with my attorney and am fully satisfied with my attorney and my attorney's advice. At this time, I have no dissatisfaction or complaint with my attorney's representation. I agree to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint I may have with my attorney's representation.

14. WAIVER OF CERTAIN DEFENSES

By signing this Plea Agreement, I waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of March 29, 2006. This waiver is binding on me only as to charges brought by the United States. This waiver expires once judgment is entered, except as set forth in the section of the Plea Agreement entitled "REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION."

15. EFFECT OF MY SIGNATURE

I understand that my signature on this Plea Agreement constitutes a binding offer by me to enter into this Plea Agreement. I understand that the United States has not accepted my offer until it signs the Plea Agreement.

16. GENERAL UNDERSTANDINGS

The parties jointly submit that this Plea Agreement and the attached Agreed Statement of Facts provide sufficient information concerning PURDUE and the crimes charged in this case to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. The parties agree to request that the Court impose sentence at the date of the arraignment and plea pursuant to the provisions of Fed. Rule Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1(a)(2), if the Court determines that a presentence report is not necessary.

If the Court accepts this Plea Agreement and sentences me to a non-incarcerative sentence, I understand that I will have no right to withdraw my guilty plea. In addition, I understand that I will not have any right to withdraw my plea if I violate my conditions of probation (if any term of probation is imposed) and, as a result, I am sentenced to incarceration.

If the Court orders a presentence report, I understand that a thorough presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

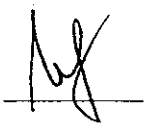
I understand that the prosecution will be free to allocute or describe the nature of this offense and the evidence in this case. I understand that the United States retains the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address the Court with respect to the nature and seriousness of the offense(s), to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court by or on behalf of the defendant.

I willingly stipulate that the Agreed Statement of Facts provides the Court with a sufficient factual basis to support my plea of guilty.

I understand that this Plea Agreement does not apply to any crimes or charges not addressed in this agreement. I understand that if I should testify falsely in this or in a related proceeding I may be prosecuted for perjury and statements I may have given authorities pursuant to this Plea Agreement may be used against me in such a proceeding.

I have not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for my plea of guilty. I understand that my attorney will be free to argue any mitigating factors on my behalf; to the extent that they are not inconsistent with the terms of this Plea Agreement. I understand that I will have an opportunity to personally address the Court prior to sentence being imposed.

This writing sets forth the entire understanding between the parties and constitutes the complete Plea Agreement between the United States of America and me, and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. This Plea Agreement supersedes all prior understandings, promises, agreements, or conditions, if any, between the United States and me.

Defendant's Initials: 

I have consulted with my attorney and fully understand all my rights with respect to the offenses charged in the Information. I have read this Plea Agreement and carefully reviewed every part of it with my attorney. I understand this Plea Agreement and I voluntarily agree to it. Being aware of all of the possible consequences of my plea, I have independently decided to enter this plea of my own free will, and am affirming that agreement on this date and by my signature below.

Date: 5/7/07

Michael Friedman, Defendant

I have fully explained to my client all rights available to my client with respect to the offenses charged in the Information. I have carefully reviewed every part of this Plea Agreement and attached Agreed Statement of Facts with my client. To my knowledge, my client's decision to enter into this Plea Agreement is an informed and voluntary one.

Date: 5/8/07

Mark F. Pomerantz
Counsel for Defendant

Date: May 9, 2007

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Case No. _____**
	)	
HOWARD R. UDELL	)	

PLEA AGREEMENT

My counsel and I have entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P.)" The terms and conditions of this agreement are as follows:

1. CHARGE(S) TO WHICH I AM PLEADING GUILTY AND WAIVER OF RIGHTS

I will enter a plea of guilty to Count Two of the attached Information, charging me with the strict liability misdemeanor offense of misbranding a drug in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1). The maximum statutory penalty for Count Two is a fine of $100,000.00, pursuant to 18 U.S.C. § 3571(b)(5), and/or imprisonment for a term of one year, plus a period of supervised release. I understand that fees may be imposed to pay for incarceration or supervised release and that there will be a $25 special assessment, pursuant to 18 U.S.C. § 3013(a)(1)(A)(iii). I further understand that any term of probation may be revoked if I violate its terms and conditions.

My attorney has informed me of the nature of the charge(s) and the elements of the charge(s) that must be proved by the United States beyond a reasonable doubt before I could be found guilty as charged.

I acknowledge that I have had all of my rights explained to me and I expressly recognize that I have the following constitutional rights and, that by voluntarily pleading guilty, I knowingly waive and give up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses in my own behalf.
The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

I am pleading guilty as described above because I am in fact guilty and because I believe it is in my best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for my plea of guilty. I agree that the Court can accept the Agreed Statement of Facts as the factual basis for my guilty plea.

I understand that the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree and stipulate that the following Guidelines' section should apply, exclusively, to my conduct:

2N2.1	6	Base Offense Level

Pursuant to Fed. R. Crim. P. 11(c)(1)(C), the parties agree to ask the Court to impose a non-incarcerative sentence. The parties agree that if the Court refuses to accept the Plea Agreement with the agreed-upon sentence I will be free to withdraw this guilty plea. In that event, this Agreement will be null and void and nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410 and the United States will move to dismiss the Information without prejudice to the United States' right to indict me or any other entity or individual on any charge.

The parties agree and stipulate that restitution is not applicable to my conviction.

If the Court were to impose a sentence that includes probation, I do not believe that any non-standard conditions of probation are appropriate. The United States agrees to take no position as to any non-standard conditions of probation.

3. DISGORGEMENT

Prior to the entry of my guilty plea, I will transfer $8,000,000.00 (eight million dollars) to the Virginia Medicaid Fraud Control Unit's Program Income Fund. If the Court rejects this Plea Agreement and, as a result, I withdraw my plea, the $8,000,000.00 (eight million dollars) will be returned to me.

4. MANDATORY ASSESSMENT AND FINE

I understand that there is a mandatory assessment of $25.00 per misdemeanor count of conviction. The parties agree and stipulate that a fine of $5,000.00, at the upper end of the guidelines' range, is appropriate for this case. I agree that I will submit to the U.S. Clerk's Office, a certified check, money order, or attorney's trust check, made payable to the "Clerk, U.S. District Court" in the amount of $5,025.00 within seven days of entering my plea of guilty.

5. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, I withdraw my plea, I agree to: (1) accept responsibility for my conduct; (2) fully comply with all terms of probation, if a term of probation is imposed; (3) not attempt to withdraw my guilty plea; (4) not deny that I committed the crime to which I have pled guilty; and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this agreement (if a presentence report is ordered by the Court).

I consent to public disclosure of all resolution documents related to this case.

I will not make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in the Agreed Statement of Facts. Should the United States Attorney's Office for the Western District of Virginia notify me of a public statement that contradicts a statement of fact contained in the Agreed Statement of Facts, I may avoid noncompliance with my obligations under this Plea Agreement by publicly repudiating such statement within two business days after such notification. Notwithstanding the above, I may avail myself of any legal or factual arguments available to me in defending litigation brought by a party other than the United States or in any investigation or proceeding brought by a state entity or by the United States Congress. This paragraph is not intended to apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative or civil case initiated by any governmental or private party against such individual.

6. ADMISSIBILITY OF STATEMENTS

I understand that any statements I make or made on my behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against me in this or any other related criminal proceeding. I knowingly waive any right I may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other related criminal proceeding. With the exception of the situations set forth above, I do not waive my right to argue against admissibility under any ground permitted under federal or state rules of evidence in any other proceeding.

If the Court rejects the Plea Agreement, and, as a result, I withdraw my plea, I will not be bound by the waivers set forth in this section of the Plea Agreement.

7. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, I agree that I will not appeal the conviction or sentence imposed. I am knowingly and voluntarily waiving any right to appeal and am voluntarily willing to rely on the Court in sentencing me pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). I agree not to collaterally attack the judgment and/or sentence imposed in this case and waive my right to collaterally attack, pursuant to Title 28, United States Code, Section 2255, the judgment and

any part of the sentence imposed upon me by the Court. I agree and understand that if I file any court document (including but not limited to a notice of appeal) seeking to disturb, in any way, the judgment and/or sentence imposed in my case, the United States will be free to take whatever actions it wishes based on this failure to comply with my obligations under the Plea Agreement.

8. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION

I understand that if: (1) I attempt to withdraw my plea (in the absence of the Court refusing to accept the Plea Agreement) or fail to comply with any provision of this agreement, at any time; (2) any defendant in this case does not fulfill the defendant's obligations under the defendant's Plea Agreement prior to the imposition of judgment; (3) my conviction is set aside, for any reason; and/or (4) any entity related to any defendant fails to execute all required paperwork or fails to fulfill its obligations to effectuate the resolution of this entire investigation prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this agreement, including, but not limited to, those obligations set forth in the section of this agreement entitled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this agreement, I will still be bound by my obligations under this agreement. I hereby waive my right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consent to the filing of an information against me concerning any charges filed pursuant to this section of the Plea Agreement. I hereby waive any statute of limitations argument as to any such charges.

9. INFORMATION ACCESS WAIVER

I knowingly and voluntarily agree to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. §552, or the Privacy Act of 1974, 5 U.S.C. §552a.

10. DESTRUCTION OF ITEMS OBTAINED BY LAW ENFORCEMENT

The United States Attorney's Office will inform me when my personal financial records and/or other records or items obtained from my accountant or any documents otherwise relating to my personal finances are available for removal. I expressly agree that, within 30 days of being informed by the United States Attorney's Office that such records are available for removal, I will remove, at my cost, all such records from the premises designated by the United States Attorney's

Office. In addition, by signing this Plea Agreement, I hereby consent to the destruction of all items obtained by law enforcement agents during the course of the investigation (other than those described above), and will execute any documents necessary to comply with this provision.

11. COMPLETION OF PROSECUTION

I understand that except as provided for in this agreement, so long as I comply with all of my obligations under the agreement, there will be no further criminal prosecution or forfeiture action by the United States against me, for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

I understand that nothing in this Plea Agreement precludes any private party from pursuing any civil remedy against me, and I agree that I will not raise this Plea Agreement or my guilty plea as a defense to any such civil action.

12. LIMITATION OF AGREEMENT

This Plea Agreement is limited to the United States of America and does not bind any state or local authorities.

13. EFFECTIVE REPRESENTATION

I have discussed the terms of the foregoing Plea Agreement and all matters pertaining to the charges against me with my attorney and am fully satisfied with my attorney and my attorney's advice. At this time, I have no dissatisfaction or complaint with my attorney's representation. I agree to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint I may have with my attorney's representation.

14. WAIVER OF CERTAIN DEFENSES

By signing this Plea Agreement, I waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of March 29, 2006. This waiver is binding on me only as to charges brought by the United States. This waiver expires once judgment is entered, except as set forth in the section of the Plea Agreement entitled "REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION."

15. EFFECT OF MY SIGNATURE

I understand that my signature on this Plea Agreement constitutes a binding offer by me to

enter into this Plea Agreement. I understand that the United States has not accepted my offer until it signs the Plea Agreement.

16. GENERAL UNDERSTANDINGS

The parties jointly submit that this Plea Agreement and the attached Agreed Statement of Facts provide sufficient information concerning PURDUE and the crimes charged in this case to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. The parties agree to request that the Court impose sentence at the date of the arraignment and plea pursuant to the provisions of Fed. Rule Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1(a)(2), if the Court determines that a presentence report is not necessary.

If the Court accepts this Plea Agreement and sentences me to a non-incarcerative sentence, I understand that I will have no right to withdraw my guilty plea. In addition, I understand that I will not have any right to withdraw my plea if I violate my conditions of probation (if any term of probation is imposed) and, as a result, I am sentenced to incarceration.

If the Court orders a presentence report, I understand that a thorough presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

I understand that the prosecution will be free to allocute or describe the nature of this offense and the evidence in this case. I understand that the United States retains the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address the Court with respect to the nature and seriousness of the offense(s), to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court by or on behalf of the defendant.

I willingly stipulate that the Agreed Statement of Facts provides the Court with a sufficient factual basis to support my plea of guilty.

I understand that this Plea Agreement does not apply to any crimes or charges not addressed in this agreement. I understand that if I should testify falsely in this or in a related proceeding I may be prosecuted for perjury and statements I may have given authorities pursuant to this Plea Agreement may be used against me in such a proceeding.

I have not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for my plea of guilty. I understand that my attorney will be free to argue any mitigating factors on my behalf; to the extent that they are not inconsistent with the terms of this Plea Agreement. I understand that I will have an opportunity to personally address the Court prior to sentence being imposed.

This writing sets forth the entire understanding between the parties and constitutes the complete Plea Agreement between the United States of America and me, and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. This Plea Agreement supersedes all prior understandings, promises, agreements, or conditions, if any, between the United States and me.

I have consulted with my attorney and fully understand all my rights with respect to the offenses charged in the Information. I have read this Plea Agreement and carefully reviewed every part of it with my attorney. I understand this Plea Agreement and I voluntarily agree to it. Being

aware of all of the possible consequences of my plea, I have independently decided to enter this plea of my own free will, and am affirming that agreement on this date and by my signature below.

Date: 5/7/07

Howard R. Udell, Defendant

I have fully explained to my client all rights available to my client with respect to the offenses charged in the Information. I have carefully reviewed every part of this Plea Agreement and attached Agreed Statement of Facts with my client. To my knowledge, my client's decision to enter into this Plea Agreement is an informed and voluntary one.

Date: 5/8/07

Mary Jo White
Counsel for Defendant

Date: May 9, 2007

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
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	)	
PAUL D. GOLDENHEIM	)	

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If the Court rejects the Plea Agreement, and, as a result, I withdraw my plea, I will not be bound by the waivers set forth in this section of the Plea Agreement.

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any part of the sentence imposed upon me by the Court. I agree and understand that if I file any court document (including but not limited to a notice of appeal) seeking to disturb, in any way, the judgment and/or sentence imposed in my case, the United States will be free to take whatever actions it wishes based on this failure to comply with my obligations under the Plea Agreement.

8. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION

I understand that if: (1) I attempt to withdraw my plea (in the absence of the Court refusing to accept the Plea Agreement) or fail to comply with any provision of this agreement, at any time; (2) any defendant in this case does not fulfill the defendant's obligations under the defendant's Plea Agreement prior to the imposition of judgment; (3) my conviction is set aside, for any reason; and/or (4) any entity related to any defendant fails to execute all required paperwork or fails to fulfill its obligations to effectuate the resolution of this entire investigation prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this agreement, including, but not limited to, those obligations set forth in the section of this agreement entitled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this agreement, I will still be bound by my obligations under this agreement. I hereby waive my right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consent to the filing of an information against me concerning any charges filed pursuant to this section of the Plea Agreement. I hereby waive any statute of limitations argument as to any such charges.

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Office. In addition, by signing this Plea Agreement, I hereby consent to the destruction of all items obtained by law enforcement agents during the course of the investigation (other than those described above), and will execute any documents necessary to comply with this provision.

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I understand that except as provided for in this agreement, so long as I comply with all of my obligations under the agreement, there will be no further criminal prosecution or forfeiture action by the United States against me, for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

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14. WAIVER OF CERTAIN DEFENSES

By signing this Plea Agreement, I waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of March 29, 2006. This waiver is binding on me only as to charges brought by the United States. This waiver expires once judgment is entered, except as set forth in the section of the Plea Agreement entitled "REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION."

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I understand that my signature on this Plea Agreement constitutes a binding offer by me to

enter into this Plea Agreement. I understand that the United States has not accepted my offer until it signs the Plea Agreement.

16. GENERAL UNDERSTANDINGS

The parties jointly submit that this Plea Agreement and the attached Agreed Statement of Facts provide sufficient information concerning PURDUE and the crimes charged in this case to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. The parties agree to request that the Court impose sentence at the date of the arraignment and plea pursuant to the provisions of Fed. Rule Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1(a)(2), if the Court determines that a presentence report is not necessary.

If the Court accepts this Plea Agreement and sentences me to a non-incarcerative sentence, I understand that I will have no right to withdraw my guilty plea. In addition, I understand that I will not have any right to withdraw my plea if I violate my conditions of probation (if any term of probation is imposed) and, as a result, I am sentenced to incarceration.

If the Court orders a presentence report, I understand that a thorough presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

I understand that the prosecution will be free to allocute or describe the nature of this offense and the evidence in this case. I understand that the United States retains the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address the Court with respect to the nature and seriousness of the offense(s), to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court by or on behalf of the defendant.

I willingly stipulate that the Agreed Statement of Facts provides the Court with a sufficient factual basis to support my plea of guilty.

I understand that this Plea Agreement does not apply to any crimes or charges not addressed in this agreement. I understand that if I should testify falsely in this or in a related proceeding I may be prosecuted for perjury and statements I may have given authorities pursuant to this Plea Agreement may be used against me in such a proceeding.

I have not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for my plea of guilty. I understand that my attorney will be free to argue any mitigating factors on my behalf; to the extent that they are not inconsistent with the terms of this Plea Agreement. I understand that I will have an opportunity to personally address the Court prior to sentence being imposed.

This writing sets forth the entire understanding between the parties and constitutes the complete Plea Agreement between the United States of America and me, and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. This Plea Agreement supersedes all prior understandings, promises, agreements, or conditions, if any, between the United States and me.

I have consulted with my attorney and fully understand all my rights with respect to the offenses charged in the Information. I have read this Plea Agreement and carefully reviewed every part of it with my attorney. I understand this Plea Agreement and I voluntarily agree to it. Being

aware of all of the possible consequences of my plea, I have independently decided to enter this plea of my own free will, and am affirming that agreement on this date and by my signature below.

Date: May 8, 2007

Paul D. Goldenheim, Defendant

I have fully explained to my client all rights available to my client with respect to the offenses charged in the Information. I have carefully reviewed every part of this Plea Agreement and attached Agreed Statement of Facts with my client. To my knowledge, my client's decision to enter into this Plea Agreement is an informed and voluntary one.

Date: May 8, 2007

Andrew Good
Counsel for Defendant

Date: May 10, 2007

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. _____**
	)	
THE PURDUE FREDERICK COMPANY, INC.	)	
	)	
Defendant.	)	

VERIFIED COMPLAINT FOR FORFEITURE *IN REM*

Now comes the plaintiff, United States of America, by and through its attorney, Sharon Burnham, Assistant United States Attorney, and brings this complaint and alleges as follows in accordance with Supplemental Rule G(2) of the Federal Rules of Civil Procedure:

NATURE OF THE ACTION

1. This is an action to forfeit and condemn to the use and benefit of the United States of America, pursuant to18 U.S.C. § 981(a)(1)(A), the following property: THE PURDUE FREDERICK COMPANY, INC. ("defendant property"), for violations of 18 U.S.C. § 1957.

THE DEFENDANT *IN REM*

2. The defendant property consists of the corporation known as THE PURDUE FREDERICK COMPANY, INC., and its assets. The defendant property has not been seized and is not located within this district, but jurisdiction is proper pursuant to 28 U.S.C. §§1355 and 1395.

JURISDICTION AND VENUE

3. Plaintiff brings this action in rem in its own right to forfeit and condemn the defendant property. This Court has jurisdiction over an action commenced by the United States

under 28 U.S.C. § 1345, and over an action for forfeiture under 28 U.S.C. § 1355(a).

4. This Court has in rem jurisdiction over the defendant property under 28 U.S.C. § 1355(b). Upon the filing of this complaint, the plaintiff requests that the Court issue an arrest warrant *in rem* pursuant to Supplemental Rule G(3)(b), which the plaintiff will execute upon the property pursuant to 28 U.S.C. § 1355(d) and Supplemental Rule G(3)(c).

5. Venue is proper in this district pursuant to 28 U.S.C. §1355(b)(1), because a criminal prosecution of the owner of the property could be brought in this district.

BASIS FOR FORFEITURE

6. The defendant property is subject to forfeiture pursuant to 18 U.S.C. § 981(a)(1)(A), because it constitutes property involved in transactions and attempted transactions in violation of 18 U.S.C. § 1957, or is property traceable to such property.

FACTS

7. The attached Agreed Statement of Facts and Declaration of Special Agent Philip Barnett are incorporated by reference.

WHEREFORE, the United States of America respectfully requests that the Clerk of Court issue an arrest warrant *in rem* pursuant to Supplemental Rule G(3)(b); that due notice be given to all parties to appear and show cause why the forfeiture should not be decreed; that judgment be entered declaring the defendant property to be condemned and forfeited to the United States of America for disposition according to law; and that the United States of America be granted such other and further relief as this Court may deem just and proper, together with the costs and disbursements of this action.

Respectfully submitted,

JOHN L. BROWNLEE
United States Attorney
Western District of Virginia

Sharon Burnham
Assistant United States Attorney

DATE: May 9, 2007

DECLARATION

I am a Special Agent of the Internal Revenue Service, United States Department of Treasury, and one of the agents assigned the responsibility for this case. I have read the contents of the foregoing complaint for forfeiture, and the exhibits thereto, and the statements contained therein are true to the best of my knowledge and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this ____ day of _____, 2007.

_____

Phillip A. Barnett
Special Agent, IRS-CID

DECLARATION OF PHILLIP A. BARNETT
IN SUPPORT OF A COMPLAINT FOR FORFEITURE

I, Phillip A. Barnett, upon my oath make the following statements under penalty of perjury:

I am a Special Agent of the Internal Revenue Service, United States Department of Treasury, and one of the agents assigned the responsibility for this case. Unless otherwise stated, the information in this affidavit is either personally known to me, or was provided to me by other law enforcement officers.

This affidavit is made in support of the filing of a complaint for forfeiture against The Purdue Frederick Company, Inc., and incorporates by reference the attached Agreed Statement of Facts. Your affiant has been involved in the investigation of The Purdue Frederick Company, Inc., since January 2003. The Purdue Frederick Company, Purdue Pharma L.P., and The Purdue Pharma Company ("Purdue") were part of a group of entities involved in the manufacture, marketing, promotion, sale, and distribution of pharmaceutical products, including OxyContin.

The Purdue Frederick Company, Inc., d/b/a The Purdue Frederick Company, was a New York corporation, headquartered in Connecticut. Purdue Pharma L.P. was a Delaware limited partnership, with the same headquarters and facilities as The Purdue Frederick Company. The Purdue Pharma Company was a Delaware general partnership owned by and co-located with The Purdue Frederick Company and Purdue Pharma L.P. The Purdue Pharma Company was also used to conduct pharmaceutical business until September 30, 2004, when the partnership was terminated. After The Purdue Pharma Company was terminated, The Purdue Frederick Company, Inc. became an owner of Purdue Pharma L.P.

On December 12, 1995, the United States Food and Drug Administration (FDA) approved OxyContin for marketing and distribution in the United States for moderate to severe pain lasting more than a few days. From approximately January 1996 until September 30, 2004, OxyContin sales were recorded by The Purdue Pharma Company. After The Purdue Pharma Company was terminated, OxyContin sales were recorded by Purdue Pharma L.P.

From approximately January 1996 to approximately June 2006, proceeds from the sale of OxyContin were deposited and flowed into various Purdue checking accounts, including an account at JP Morgan Chase. The JP Morgan Chase account served to aggregate the receipts of all products sold by the related Purdue companies, including OxyContin.

From 1995 to June 2006, Purdue had OxyContin gross sales of approximately $10.2 billion, with sales net of rebates and discounts totaling approximately $8.4 billion. Federal and state health care programs were among the purchasers of OxyContin and paid for OxyContin prescriptions filled at pharmacies, including pharmacies in the Western District of Virginia. The pharmacies received the monies via mail and/or wire. The pharmacies paid the wholesalers for their supplies of OxyContin via mail and/or wire. The wholesalers paid Purdue via mail and/or wire payments.

From 1995 to September 30, 2004, The Purdue Pharma Company made distributions of approximately $2,854,760,301 (two billion, eight hundred fifty four million, seven hundred sixty thousand, three hundred and one dollars) in profits, including OxyContin proceeds, via wire transfers between Purdue-owned accounts at JP Morgan Chase to The Purdue Frederick Company and Purdue Pharma L.P. All transfers of funds relied upon by the government exceeded $10,000. Although OxyContin sales receipts were co-mingled with other funds, OxyContin receipts comprised up to 90% of the total receipts.

Based upon the preceding facts, information and evidence gathered as a result of the investigation, your affiant contends there is sufficient probable cause to believe that violations under 18 U.S.C. § 1957 have been committed by The Purdue Frederick Company, Inc., supporting the complaint for forfeiture pursuant to 18 U.S.C. § 981(a)(1)(A).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this ____ day of _____, 2007.

_____
Phillip A. Barnett
Special Agent, IRS-CID